# “Lupin Limited Q1 FY20 Earnings Conference Call”

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**MANAGEMENT:** **MR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**
**MS. VINITA GUPTA – CHIEF EXECUTIVE OFFICER, LUPIN LIMITED**
**MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
**MR. RAJEEV SIBAL – PRESIDENT - INDIA REGION FORMULATIONS, LUPIN LIMITED**
**MR. NARESH GUPTA – HEAD - API PLUS, LUPIN LIMITED**
**MR. SUNIL MAKHARIA –PRESIDENT – FINANCE, LUPIN LIMITED**
**MR. RAJIV PILLAI – SR. VICE PRESIDENT - CORPORATE PLANNING, LUPIN LIMITED**
**MR. ARVIND BOTHRA – HEAD, INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**

**Moderator:** Ladies and gentlemen, good day and welcome to the Lupin Limited Q1 FY '20 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 the operator by pressing'*' and 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, sir.

**Kamal Sharma:** Hello. This is Kamal Sharma. It is pleasure to welcome you to this call. I have with me Vinita, Nilesh, Rajeev Sibal, Naresh, Rajiv Pillai, Arvind, and Sunil Makharia, who would help us walk through the questions that you would have.

As you would've seen, we had a good quarter. The corresponding sales increased by 15.4%YoY. Sequentially sales were largely flat, 0.7% increase. Profit has increased by 49.5% YoY. And even sequentially profit went up by 5.4%. EBITDA was up by 31% YoY, though it was slightly lower on a sequential basis. You will get to know the reasons for the same. With those opening words, I would like to hand it over to Rajiv Pillai to walk you through the numbers. And then we'll open the floor for questions and answers. Thank you, Rajiv.

**Rajiv Pillai:** Thank you, Dr. Sharma. Good afternoon, friends. I am pleased to share the results, which were uploaded yesterday on our website and the stock exchanges.

Sales for Q1 FY '20 were Rs. 4,356 crores which represents a 15.4% growth YoY. As Dr. Sharma alluded, sequentially it has been largely flat. This growth has been secular across most of our geographies, led by the U.S. and followed by India. U.S. showed 30% YoY growth and India, delivered strong growth once again at 12% YoY in the branded generics segment. All other geographies also contributed very well.

As far as gross margins go, they also showed an improvement at 64.4% as opposed to 61.7% in the previous year. I would attribute this to better business mix, higher sales in the U.S. and better product mix.

EBITDA for the quarter stood at 21.4% compared to 18.8% in the previous year, which is again, a meaningful improvement that we have talked about in the past.

R&D stood at 8.7% to sales and like we have spoken in the previous quarter, our commitment is to keep this below 10%. We expect some gradual ramp up, but we will be there and thereabout. Fx did not have a meaningful contribution, on the P&L line this quarter around. Employee benefits, we see the YoY increase of 7.7%, largely on account of annual increments. You would see that for other manufacturing expenses there is a number which is lower sequentially. However, I would attribute that to mostly phasing out the expenses. ETR for the current quarter is trending around 43%. Like we said in the past, we were targeting around 40% annually. That's all from my side.

**Nilesh Gupta:** We are happy to take questions now.

**Moderator:** Thank you. Ladies and gentlemen, 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:** If you could help us, update on the regulatory front, and our expectation in terms of the closure of remediation and approval of facilities of Goa and Indore please?

**Nilesh Gupta:** Sure. Prakash. As we have talked before, we built a compliance sustainability plan through which we've been updating the FDA on a regular basis for all our OAI sites. Specifically, for Goa and Pithampur, we have been sending in regular updates, and I think we've made significant progress with the FDA. We feel that the one big issue, that we still need more work on, is the area of OOS investigations and we have a very solid plan around there. The plan is to work on this for the next few months and in about 6 months to be ready for a re-inspection for the 2 sites.

**Prakash Agarwal:** Okay. And do you expect them to happen simultaneously?

**Nilesh Gupta:** I think it's a little premature for that. We'll see how we open up these sites for reinspection.

**Prakash Agarwal:** Okay. Perfect. And second question, on the other expenses, I think Rajiv mentioned, there has been some phasing out. And if you could help us understand what's the Forex impact here? Is there a Forex loss sitting? And if there's any Ind AS impact sitting there?

**Rajiv Pillai:** Like I said earlier, the Fx impact is not very meaningful, it's fairly low. On Ind AS, we are compliant with Ind AS 116, and on the EBITDA line, the impact is around 0.9%.

**Prakash Agarwal:** Okay. And the corresponding impact has been captured in the depreciation line

**Rajiv Pillai:** That is right.

**Prakash Agarwal:** Okay. So, that would be a similar 0.9% impact, just to clarify?

**Rajiv Pillai:** Yes.

**Prakash Agarwal:** Okay. And lastly, on the U.S., you earlier talked about $850-plus million in the U.S. with about 20+ launches. So, are we on track with that?

**Vinita Gupta:** Yes, Prakash we feel good about the 20+ launches This quarter, we launched 5 products including interesting ones like Budesonide as well as Testosterone Gel. So, we feel pretty good about the 20+ launches. As we look at the growth of the U.S. business, on the one hand, the base business has stabilized. The team has worked hard to stabilize it at that $180 million-plus. ranolazine has made a very significant impact in Q1 but has now come down. As we look at Q2 and the rest of the fiscal year, levothyroxine is a big driver of growth for the U.S. business. Also

in Q2, we would launch our injectables portfolio in the U.S. We have not really materially participated in the injectables segment so far. We have a first launch for Fosaprepitant in September and a couple of other injectable products around it. So, looking forward to delivering growth in the U.S. market.

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

**Surya Patra:** Ma'am, if you can just indicate for the quarter, what is the branded revenue in the U.S.? And again, on the US growth outlook from the ex-Ranexa, you already mentioned that okay, the injectable portfolio that would be launched in the Q2 in U.S. So, what is the kind of growth outlook that you're building, whether you're still believing there was a double-digit kind of growth in the U.S. portfolio overall?

**Vinita Gupta:** The branded revenue grew roughly 40% QoQ. Majority of the focus on the brand side of the business right now is in Solosec. Solosec per se on a scrip level grew just over 20% QoQ. And as I mentioned, as far as growth outlook for the fiscal year, we had a strong start in Q1 with gRanexa. We have had a small amount of levothyroxine in the quarter. We expect levothyroxine to ramp up significantly over the years. We should have some growth in Q2 with more so in Q3 and Q4, as our capacity ramps up and gives us the ability to take on all of the customers that we have targeted. So, that would certainly be a significant growth driver. And then the injectable portfolio that I mentioned we will launch at the end of this quarter. That should really contribute pretty well in the second half of the year. We feel pretty good about not double digits, but at least single digit percentage growth for the fiscal year.

**Surya Patra:** Is it possible to give some more color on the injectable portfolio that you're indicating for the second quarter launch?

**Vinita Gupta:** Yes. The anchor product is Fosaprepitant. That goes off patent in September, and that's a day 1 launch. Around it, we are launching other smaller products like Doxercalciferol, Decitabine and Azacitidine oncology products. So, really pleased to be able to get into the injectable market with these products.

**Surya Patra:** Okay. And about the India Formulations business, see we have definitely delivered a kind of near 10% growth for the quarter. But in the light of the Jan Aushadhi thing and that is picking up and even the online pharmacies playing an important role now in the domestic side. So, what impact that you are witnessing for the overall domestic formulation trend and particularly for Lupin going ahead?

**Rajeev Sibal:** So, if you look at India business this quarter, actually, our branded business has grown by 12.3% YoY. So, if you look at the drivers of this growth, our volume growth has been strong at 4.7% against the industry volume growth of 1.7%. Jan Aushadhi and e-pharmacies are obviously

picking up, but right now, their penetration is small. I don't think that we have been impacted to that an extent. And looking at our product portfolio, our in-licensing strategy, I'm pretty sure that even in coming quarters also, Lupin India business will continue to grow at the pace what it is growing.

**Surya Patra:** Okay. But by any chance, you see some pricing pressure or something like that, sir?

**Rajeev Sibal:** So, on the e-pharmacies, right now, as I said, penetration is very small. But yes, once the new law comes as far as pharmacy is concerned, once the penetration goes up, obviously, there will be some pricing pressure. But right now, I don't think any pricing pressure is being seen to that an extent.

**Moderator:** Thank you. The next question is from the line of Arjuma Begum from Course5. Please go ahead.

**Arjuma Begum:** I have a few questions. First on generic Brovana. In the Annual Investor Meet which was held on May 2019, it was announced that generic Brovana has been filed. So, are you engaged in any certain litigation case which is with a bigger company? Or is your filing accepted? And did you get any TAD for the same?

**Vinita Gupta:** We had filed, and our filing has been accepted. I don't believe that we are involved in any litigation right now. And I don't recall the TAD off the top of my head, but that should potentially be a near-term opportunity if some of the other players that are ahead of us open the market for the product.

**Arjuma Begum:** Okay. And second, on generic Spiriva. Do you have any update on Spiriva litigation process, when you expect it to be resolved? And do you have any TAD for the same?

**Vinita Gupta:** So, it's pretty early from a litigation standpoint as we only filed the product in May last year. Our target date is November '2020.

**Arjuma Begum:** And the last question is about generic Advair. The deal was made with Celon in Feb 2015. How the product is progressing in the pipeline? And when can you expect to launch in the market?

**Vinita Gupta:** So, we are late in generic Advair, as we have mentioned in the past quarters. We continue to work with Celon to develop the product, and simultaneously track the market very closely to make sure that the market opportunity still remains attractive for us to continue investment. We are still at the PK level. Once we pass that stage gate, at that point in time, we will determine what the exact timeline is to develop and launch the product.

**Arjuma Begum:** Okay. And lastly, I have one more question. For ICS/LABA drug two products like Advair and Symbicort are available in the U.S. market as Mylan already has a generic as well. So, do you still see Advair as an opportunity? Or would you like to develop generic Symbicort?

**Vinita Gupta:** We're developing Symbicort as well. And so far, as we look at the market evolution after the launch of generic Advair, we haven't seen a material switch from Advair into other molecules. So, we still see other products like Symbicort have very attractive opportunities and distinct from Advair.

**Moderator:** Thank you. The next question from the line of Neha Manpuria from JPMorgan. Please go ahead.

**Neha Manpuria:** Ma'am, on Solosec, we indicated we're now taking certain specific actions to try to push the penetration or increase prescription growth in the quarter. While you indicated 20%, is it now tracking in line with what we had expected? Or do you think it requires more work to achieve what we had thought about for Solosec for the full year?

**Vinita Gupta:** Neha, I think I could say that it's now on track. We are pleased that we are making progress quarter after quarter and have grown scrips. We are on the right path, but we need to accelerate growth. There is a continued effort to drive tactics from a salesforce standpoint, from a targeting standpoint, direct-to-patient standpoint to drive a higher level of growth. I'd say it's progressed, but more to come.

**Neha Manpuria:** Do you think incremental action would be required from our end? Or just that the initiatives that we've taken could take time?

**Vinita Gupta:** Actually, we have. in the last couple of months. really optimized our tactics quite a bit. Given the 1-year experience with the product, we took a step back and took a look at our targets and had the opportunity to refine our targets, so that we could actually leverage our strong managed care coverage better. We have recently also added on the direct-to-patient front and on the digital direct-to-patient strategy. We have Solosec on Facebook that just went live in the last 2 weeks. We have a voucher program that we put in place for physicians, especially high-volume physicians that have not written the product to encourage trial. So, there are a lot of efforts ongoing, that our team has put in place in the last 2 months. The results of those are yet to be seen.

**Neha Manpuria:** Fair enough. In terms of the Women's health portfolio, right? I am assuming we will have to add assets to eventually look at breakeven for the branded business. And are we evaluating assets? Is there anything interesting available in the market on the Women's health side to augment that portfolio? Because with Solosec, longer-term would Women's health focus make sense?

**Vinita Gupta:** We certainly intent to add to our Women's health portfolio and are actively looking at opportunities- to partner, co-promote or acquire products. There are a few on the table that we are looking at right now. Hopefully, within this year, we will be able to bring at least one opportunity to expand our portfolio and offset some of the commercial expenditure.

**Neha Manpuria:** Understood. And one last question, if I may. levo, you mentioned the quarter-on-quarter contribution was a little bit. With the approval for the other 2 RLDs pending, is the second half ramp up dependent on approval of those 2? Or you think even with the existing approval, we can see ramp up in levo?

**Vinita Gupta:** We will definitely see ramp-up, but ramp-up is also based on capacity ramp-up. We are going about it very strategically and we want to be able to meet the commitments that we give to our customers. The majority of commitments that we have made are pretty large volume customers, as you can imagine. Some of our partners are also waiting for approval for all 3 RLDs which is expected in Q3.

**Nilesh Gupta:** If I can just add, we are maximizing our production and are currently running to capacity. We feel that we need to build up those volumes so that we can take good bites at market share as well.

**Neha Manpuria:** And that is likely to happen in the second half.

**Nilesh Gupta:** Yes.

**Moderator:** Thank you. The next question is from the line of Hari Belawat from Techfin. Please go ahead.

**Hari Belawat:** This is regarding recall of certain medicines, I think 12,000 cartons were recalled, Fayosim medicine in the U.S. That was in month of April or so. What is the legal and financial implication of such a recall?

**Vinita Gupta:** Financially it obviously costs us to do the recall. We have to offset our sales since it's a product sold to the channel partner. And there is a cost of the recall to the trade that we have to bear. But from a legal and compliance standpoint, it's a very strong position. A more conservative position, so that we don't have any risks or any exposure, especially from a patient standpoint.

**Hari Belawat:** But generally, these recalled medicines which are having certain problems, at what stage do we know if it has gone to pharmacy and then you get it back? And how is the process occurring there?

**Vinita Gupta:** We track the product through its life. Depending on what we learn over time about the product and the samples that we retain, we determine if there's any risk from a patient perspective, which requires us to take a position and recall a product.

**Hari Belawat:** Okay. Has there been any case other than this, which was just recalled?

**Vinita Gupta:** There have been unfortunately multiple recalls over the last many years, not only for us, but for the rest of the industry as well. It's just a part of the pharmaceutical process. You learn about the

product as you gain experience with it. As you learn more about it, you get wiser and can revise and take actions necessary to ensure patient safety.

**Moderator:** Thank you. The next question is from the line of Subhankar Ojha from SKS Capital. Please go ahead.

**Subhankar Ojha:** How is Lupin benefiting from some of the generic product basket restructuring that has happened in U.S.? And how much percentage of our U.S. generic will fall in that category?

**Vinita Gupta:** We have proactively built share on our baseline products as some of our peers/competitors have exited portfolios. I won't be able to give you exact percentage of our base business, but it's fair to say that our team has been able to build up a strong base of that $180-million-plus level. It has been both a combination of our solid foundation and then opportunistically gaining share wherever it made sense when others exited.

**Subhankar Ojha:** Okay. But do you think the other players may come in and fill in that space? Or do you have a good opportunity there?

**Vinita Gupta:** We believe that there is a level of rationality that has fed into the U.S. generic market. On the one hand, we see that the customer consolidation for the most part is behind us. We've also seen a number of companies exit portfolios like Mylan, Teva, Sandoz and we've seen a smaller number of ANDAs being filed. Companies are being more judicious with their pipeline. We have also seen that in hyper-competitive products, you don't see every company launching their product. So, companies are getting very judicious about product launches, product filings, investments in products, which makes for a better, healthier environment for the generic industry.

**Subhankar Ojha:** Okay. And secondly, what is the status of Gavis portfolio? I mean, when do we plan to utilize that portfolio to its true potential?

**Vinita Gupta:** So, we are leveraging the potential as we speak. I mean, the business has grown over the past year and through this fiscal year as well. Quarter-on-quarter, we expect to grow our share of our products out of the Somerset facility. We also have a number of good filings, multiple first-to-files that we made in the last 2 years at the site. And I am hoping that we will be able to clear the OAI at the site soon, hopefully this fiscal year so that we can leverage those opportunities next year onwards.

**Subhankar Ojha:** Okay. And lastly, if I may, when do you plan to launch the first inhaler, Tiotropium?

**Vinita Gupta:** Tiotropium is a 2023 launch as it stands right now.

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

**Nitin Agarwal:** Vinita, any updates on the ProAir launches for which you are looking at an approval in second half?

**Vinita Gupta:** We are looking to get feedback from the FDA. Actually, the review of the application at the FDA has taken longer than anticipated. Our goal date was moved by a few months. We are hoping to get some feedback from the agency soon, in the next couple of weeks and then we'll be able to determine how soon we should be able to launch the product.

**Nitin Agarwal:** And this delay, I mean, do you see it changing fundamentally the fact that authorized generics are already in and the fact that if the generic approvals get delayed, does it make the job a little difficult for anyone of the generic to, whenever they get launched, to claw back market share?

**Vinita Gupta:** We don't think so. We think the market opportunity remains pretty attractive. If you look at the relative pricing of the authorized generics, it is roughly at the same level as a discounted brand. If you look at the share of the 3 brands and their authorized generics, it is relatively the same as it was prior to the launch of AG. As we look at pricing at present as well as the market opportunity, it still remains very attractive. So, we hope that we can launch the product in the second half. It looks like Q3 will be tough at this point, given that we are already in August and waiting for feedback from the agency. We have materials ready to start manufacturing product, but don't want to lose dating. We think that at this point in time, it will likely be a Q4 launch, and even though the launch gets delayed by a quarter or so, we still think it should be fairly attractive.

**Nitin Agarwal:** Okay. So, I just want to confirm 2 things that you mentioned earlier in the call. You said our base business stabilized around $180-odd-million now, right? I got it right?

**Vinita Gupta:** Yes.

**Nitin Agarwal:** Yes. So, Ranexa still was the largest component of this quarter for us. It was lower than last quarter, but still, it's a reasonable component for this quarter's numbers, in the year.

**Vinita Gupta:** That's right.

**Nitin Agarwal:** Okay. And secondly, on the branded business, outside of Solosec, is there anything much to really look forward in the balance part of the portfolio or our focus is entirely on Solosec now?

**Vinita Gupta:** The focus is very much on Solosec. The other products, Antara and Cefixime (both the capsule as well as the suspension), have gone generic. Antara has some topline and bottom-line that offset some of our spend. But, the majority of the focus is on building Solosec.

**Nitin Agarwal:** And lastly, just alluding with one of the earlier questions. Do you still see meaningful volume expansion opportunities for our existing portfolio or given that we have pretty large market shares in a fraction of our market products?

**Vinita Gupta:** No, there's a good number of products where we are the market leader and have a top 3 position, but there is a good product portfolio where we are not. So, the team is certainly working very hard to look at every product and try to determine if we have an opportunity, in a profitable way, to gain share to be in the top 3. So, there certainly is an opportunity. We think that with the kind of consolidation that is taking place in the U.S., with the recent Mylan transaction, I'm sure there's more to come. There will be opportunities that come to players like us.

**Moderator:** Thank you. The next question is from the line of Tushar Manudhane from Motilal Oswal Securities. Please go ahead.

**Tushar Manudhane:** Just on the levothyroxine for the other RLDs. So, in terms of queries, where do we stand?

**Nilesh Gupta:** We have no pending queries. And likely by Q3, we should have approval for the other RLDs.

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

**Chirag Dagli:** Can you quantify the U.S. brand sales for the first quarter?

**Vinita Gupta:** It's around $5 million.

**Chirag Dagli:** And currently, there is definitely a revenue and cost mismatch in terms of what you're investing in this facility. Is there a number that you want to share with us of what sort of EBITDA hurt is this effort causing us?

**Vinita Gupta:** I don't think we want to share a product-specific investment number. But it's fair to say that this is a long-term investment for us. We believe in the potential of Solosec as well as the Women's health business. We have a long runway with Solosec over the next 8 years, plus we have own lifecycle management in place. While we want to get to breakeven as soon as possible, our effort is to ensure that we build the product in a way that it builds long-term loyalty with physicians as well as patients.

**Chirag Dagli:** The digital strategy does not increase the costs meaningfully, right?

**Vinita Gupta:** Not materially. It is not TV advertisement, it’s really a direct-to-patient through social media, bloggers. We have a Facebook page now in place. And for this condition, a lot of them intend to go to resources like this as opposed to talking to their physicians. We really want to encourage patients, women to get awareness about the condition and go to the physician and ask for Solosec. That's the goal with our digital strategy.

**Chirag Dagli:** Right. And the second question I had was on these products that where some of the larger players are leading market share. So, what happens to the prices of these products based on whatever you've seen over the past 1 year? What has happened to prices of some of these products which have gone into either rebidding or people have withdrawn products?

**Vinita Gupta:** Well, there's always an opportunity to reset pricing when anybody exits the marketplace. So, from our standpoint, if it makes sense, if its profitable, we would add share. If not, we will not enter the product. But we've seen more opportunities where pricing has been more rational after companies have exited, and that has allowed us to gain share on a profitable basis.

**Chirag Dagli:** More rational means there is naturally an increase in the existing price?

**Vinita Gupta:** That's right.

**Chirag Dagli:** Can you quantify just a ballpark, sort of broad range?

**Vinita Gupta:** It's hard to quantify.

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

**Sameer Baisiwala:** We have a couple of clarifications. One, on Spiriva, you said 2023 launch, is it fiscal or calendar? And I'm asking because I saw the key patent expires in 2022.

**Vinita Gupta:** Yes, well it is around the key patent, Sameer.

**Sameer Baisiwala:** Okay. Got it. Second is question on Albuterol. Now my guess is 3 authorized generics have taken 35% - 40% market share. Is that also remain an addressable market for you? Or is it the balance branded that you would be going after?

**Vinita Gupta:** No, the entire market branded as well as authorized generic is available to us.

**Sameer Baisiwala:** Okay, great. And on levo, what's the current capacity utilization that you are having?

**Vinita Gupta:** 100%.

**Nilesh Gupta:** We are running at 100%, but we are expanding the capacity as well. In fact, we're adding an extra plant. So, we'll have a very significant ramp up.

**Sameer Baisiwala:** Okay. But if I see your prescription share that my guess is still under 5%.

**Vinita Gupta:** That's right. So, we are ramping it up very strategically, Sameer, because each of our customers is >10% points, right? So, as we ramp up capacity, we are giving them our solid commitment.

So, we expect to really be at that 20% at the end of the fiscal year from a capacity and ability to take share.

**Sameer Baisiwala:** That's great. And when does the new facility exactly start commercial production?

**Nilesh Gupta:** So, hard to comment on this area, it moves a little bit. But basically, Q4 is when we will have very good set of capacities online.

**Sameer Baisiwala:** And any update on Etanercept for Europe?

**Vinita Gupta:** Europe, actually, we've got queries from the EMA, they wanted to do some additional inspections around the PK study, and we have scheduled that for later this calendar year. So, we expect approval of the product really at end of this fiscal year, probably first quarter next fiscal year. So, our plan in the current year, is to really maximize Japan. Our partner Yoshindo has already launched and Nichi-Iko is building launch quantities, so we're working with them to get ready to launch the product in November. And then end of Q4, early Q1 fiscal year 20-21 is when we would expect Mylan to launch in Europe.

**Sameer Baisiwala:** Just with your permission one last question on Solosec. Now, Vinita, I think couple of points, you had earlier mentioned that it was not widely available in pharmacy. So, a) has that been fixed? And b) what is really the key bottleneck over here? Why do you need to go to patient directly? When patient comes to the physician, are they not happy prescribing this product and is reimbursement a bottleneck there?

**Vinita Gupta:** The number of women that actually get bacterial vaginosis is 20 million plus. And the number of prescriptions that are dispensed for bacterial vaginosis is 6 million. So, there's a huge gap in the market and the number of patients that are being treated. Therefore, the reason to really educate patients, educate women on the condition and the fact that there is a drug available that is easy to use, it's one dose treatment to draw them to the doctor's office. We find that a number of patients tend to ignore it, that's why you have this gap between 6 million and 20 million. And while our sales force is focused around the physicians and around the 6 million current prescriptions that we are working to switch share from, we also want to be able to build a wellness in the rest of the market to be able to expand the market. In terms of the other challenges that you mentioned, like pharmacy, pharmacy availability is less of a challenge. But to ensure that the pharmacy adjudicates the scrip in the right manner to ensure that we leverage our strong managed care coverage and then apply the co-pay card effectively is something that they're still learning to do. So, there is an intensified focus actually around pharmacies as well, in addition to the physicians, to ensure that the pharmacies dispense the product after taking into consideration the patient's managed care coverage plus then giving them the benefit of the coupon.

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

**Rahul Sharma:** Just wanted you to please take us through, as Ranexa is probably on the way down. What are the opportunities in FY '20 and '21 will be able to basically fill the gap apart from Etanercept and on the generics space particularly?

**Vinita Gupta:** So, as I mentioned earlier, levothyroxine is a big opportunity for us this fiscal year, but also for the next few years. Just given the complexity of the product and the supply chain, we believe that we should be in a very strong position to benefit especially on the generic side of the business in the next couple of years with levothyroxine. Other than levothyroxine, certainly albuterol depending on the FDA approval timeline, hopefully second half of this fiscal year as well as into next fiscal year, it should be a strong contributor. Our injectable portfolio, starting with Fosaprepitant that we would launch this quarter, we expect to build that up in the next couple of years. I mean, the material products there will come when new depot injectables or peptides or iron products out of Netherlands and India come online. But at least in the near term, this will allow us to gain from the hospital channel, which we have not accessed so far. So, those are a few.

**Nilesh Gupta:** And then we obviously have the 20-odd products that we still launch every year and each one of them adds a few million.

**Rahul Sharma:** The injectable portfolio will be launched starting from when?

**Vinita Gupta:** September this quarter.

**Rahul Sharma:** And which are the key products which you mentioned apart from depot injectable?

**Vinita Gupta:** For this quarter, it will be Fosaprepitant.

**Moderator:** Thank you. The next question is from the line of Nikhil Mathur from Ambit Capital. Please go ahead.

**Nikhil Mathur:** I have a question around the EBITDA margins in Q1. Now if I look quarter-on-quarter, the employee cost has been flat, and the other expenses are down quarter-on-quarter. So, is cost control a really big focus area for Lupin in FY '20 and if yes, what kind of levers that can help you to control your costs in second half FY '20?

**Nilesh Gupta:** First of all, cost control is a big lever, but I don't think there is much that has kicked in to that Q1 number. There's a little bit came into Q1, but I think Q2, more importantly in Q3, Q4 is when we get good cost savings and the following year is when we will get even more.

**Nikhil Mathur:** And second question would be on Solosec. I understand that there's a digital strategy around promoting Solosec in the U.S. But on the sales force reps front in the U.S., do you need to add more sales force reps to push the products in the market?

**Vinita Gupta:** So, once we get to our optimal share with the existing sales force, certainly we will consider adding to our sales force. There is definitely a potential, we have additional targets that would still make sense after we have gained traction with the existing sales force.

**Moderator:** Thank you. The next question is from the line of Damayanti Kerai from HSBC. Please go ahead.

**Damayanti Kerai:** My first question is can you share your growth outlook for your India formulation business as well as the overall industry outlook as per you if you look at like recent weak volume in the market, how do you see your portfolio to grow here?

**Rajeev Sibal:** As far as Lupin India business is concerned, as we said earlier that in the first quarter, we have grown at 12.3%, and wherein the volume growth was 4.7% as compared to IPM volume growth of 1.7%.We continue to see similar performance even in the coming quarters because we are very strong as far as our portfolio is concerned. Our portfolio basically is in chronic focused, as 60% of our business comes from chronic portfolio, whereas if you look at the industry, the IPM contribution to chronic is only 35%. So, since we are very strong as far as our portfolio is concerned, we are very sure that we will continue to perform at the way we have performed in first quarter in the next 3 quarters also.

**Nilesh Gupta:** And if I can just add, there are 2 or 3 areas which are very big areas for us. TB is where we started, but inhalation is a very big area, cardiovascular, diabetes and we still believe that there is room to grow. There's market share to be gained in each of these 3 as well. We have created 3 new divisions in the last 6 months. There is a lot more to come. We are very bullish for India.

**Damayanti Kerai:** Next, moving on to some of the smaller markets, though they might not be very significant to your portfolio, but if I look at the market like South Africa and all, they have seen a significant drop in sales quarter-on-quarter and in the Middle East also. So, can you just update what is happening there? And how do you see this part of the business moving ahead?

**Vinita Gupta:** South Africa is actually not too small; I mean it's the 4th largest market for us and significant. So, the first quarter, definitely had a dip, but that was more to do with phasing. We had significant sales in Q4 last fiscal, that was primarily due to the price increase that took place in April, there was 3.5% plus price increase that we saw after a long time in South Africa, because of which, there was a big trade buy in March. And that is why Q1 was short. But when we look at the secondary sales within South Africa, our sales are between 6.5% to 8% right now. We had a couple of products where we had product discontinuations as well due to supply issues. But if you put them aside, our secondary sales were at 8% growth. We feel pretty strong about growth prospects in South Africa. The current fiscal year certainly will be a good growth year for us in

South Africa. The Middle East on the other hand was insignificant for us. It was a very small part of our revenues, a couple of crores. We saw certain risk exposure from a payment perspective in the region and didn't think it was worth it, so decided to wind it down. We have a presence across many very strong geographies right now and decided to focus on our key geographies as opposed to just spreading ourselves everywhere.

**Damayanti Kerai:** Sure. Last question on the Japan, you mentioned we have seen good traction in the Enbrel launch. So, apart from that, how is the other part of the business doing there?

**Nilesh Gupta:** It's still early days, as far as that is concerned, it will be more of a build in Q3 and Q4. At the first level, Japan is the second largest market in the world. But it is going through significant pricing pressures. There is a price adjustment that will happen in October. There is another one that will happen in April, and then it's going to be an annual event thereafter. So, there are definitely pricing pressures. But I think that's when the play for an integrated generic company comes in. So, we are increasingly doing more research out of India, manufacturing out of India and supplying to the market. We need to do a lot more of that. We have moved from rank from #6 to #5, so we actually have a significant position in Japan. The volume growth will happen, but the value growth will be muted as far as Japan is concerned, but we need to bring cost efficiencies and operational excellence into the structure, which is something that we worked on. Last year, we realigned some of the sales force, we have done other measures as well. There's an efficiency play in Japan. There's obviously a specialty play as well. We have Bipresso that is picking up, still very small, but picking up significantly, it is 3 times up in the last year, good increase there as well. But all of this together, Japan's about 14% of our sales, so it's a significant portion. We have to make sure that we are successful there. So, with all these measures that we have with more of a pipeline from India, with more of a differentiated pipeline, with cost efficiencies, that is the play that we are going to have in Japan.

**Damayanti Kerai:** Sure, but the pricing environment remains very challenging there, right? And we haven't seen any improvement happening.

**Nilesh Gupta:** No, I don't think there's going to be a change on that count. It's a structural change, they used to do price cut every 2 years, they're going to bring it down to once a year. Obviously, the extent of the annual price cut will come down. But definitely, the pricing pressure will remain.

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

**Shyam Srinivasan:** Just 2 quick ones. One, this quarter, again, we saw R&D come in much lower than Q4 and Q3 as well. So, what are we doing here? I know we have signaled our intent to keep this under control. But do you think at some point of time this will start ramping up again, or do you think the high investment phase in R&D is behind us?

**Nilesh Gupta:** We've already talked about the outlook for the year as far as R&D. It's going to be a very similar number to the number that we did for last year. There's nothing different that we are doing at this point of time. I don't think we're giving up on opportunities. We've already optimized, we've resized the R&D team. We're focused much more on injectables and on the complex products. So, it sets the same story panning out at this point of time. The generic part is pretty well set, the biosimilar part is pretty well set as well. There is a little bit of increase that we should do over time on the Specialty front. We've started the first few products. Some of them will move into the clinics next year. We have to provide for that as well. But all of this together for this year, pretty much the same number as last year for next year, probably a slight increase, but still well within 10% of sales.

**Shyam Srinivasan:** And my second question is on just the U.S. market. And just from an industry perspective, what are we seeing in terms of price erosion, your kind of discussions with the supply chain. If you can share some color, that'll be very helpful.

**Vinita Gupta:** Yes, it has been fairly stable over the last few quarters, last 3 or 4 quarters have been fairly stable. And with the kind of consolidation that you're still seeing on the manufacturing front, you look at Mylan, Upjohn for example, and probably more to come. That is a positive from a supply standpoint. We expect it to continue to be stable. The price erosion, before we had the significant pressures for the last few years was in the single digits, mid-single digits, and that's where it's at right now.

**Shyam Srinivasan:** Got it. And last question is on the CAPEX. What's the guidance for this year, we have done about 120 crores. I'm just wondering the guidance for this year?

**Nilesh Gupta:** It's about 600-700 crores. Obviously, we're in that cycle where capital expenditure is limited and primarily for new areas. We have an inhalation plant that is coming up. We have a biosimilar expansion that is going on as well. So, those are some of the investments.

**Moderator:** Thank you. The next question is from the line of Sravanthi B from Infinity Research. Please go ahead.

**Sravanthi Bandaru:** So, this is regarding generic Brovana. This is the first nebulized product in your product portfolio, was it difficult to develop this product, and which manufacturing facility is responsible for this product?

**Vinita Gupta:** It was developed by our inhalation team led out of Florida and its contract manufactured in the U.S.

**Sravanthi Bandaru:** Okay. And one more thing. On generic Brovana, this will be the first company to file for generic Brovana?

**Vinita Gupta:** No, there are other companies that have filed generic Brovana as well.

**Moderator:** Thank you. The next question is from the line of Aditya Khemka from DSP Mutual Fund. Please go ahead.

**Aditya Khemka:** Actually, I have 3 questions. So, the India business growth numbers that you gave out 12.3%. That's the secondary audit growth. Correct?

**Rajeev Sibal:** No, that is the internal company or primary growth. The difference between 12.3% and 9.8%, which you see as far as results are concerned is because of our generic business, which contributes only 5% to our business. And because of that, we have some challenges of growth there, because the market is predominantly acute business. And in rural areas, that business has degrown by 8%. Otherwise, our main prescription business has grown by 12.3%.

**Aditya Khemka:** Understood. Can you elaborate a bit on this please, because what we're seeing is in the straight generic business, almost all your peers are reporting similar disruptions be it Cipla, be it Alkem etc. What really is happening in that space? And why is the business getting disrupted all of a sudden?

**Rajeev Sibal:** As I said, if you look at overall market of acute business is also low in the first quarter because of the seasonal changes. Generics is purely acute business and it is in those towns where normally our medical representative is not there, that is how this model has been built up. So, the first quarter has been impacted because of that. I'm sure, in this quarter, we should be able to stabilize as far as that part of the business is concerned.

**Aditya Khemka:** Could you also elaborate on the potential impact that you are seeing from some of the initiatives like the Jan Aushadhi or online pharmacies, how are they impacting your business growth?

**Rajeev Sibal:** I think I have said earlier also that yes, Jan Aushadhi which has now almost 4000 stores as far as pan India is concerned, and e-pharmacies, where the penetration is very low. Right now, we don't see much impact. But yes, in future, once the penetration goes up, we will surely have price erosion because then there will be in a state where they will be able to negotiate the pricing as far as products are concerned. So, right now, if you look at in the next 1- 1.5 years, I don't see much impact as far as e-pharmacy or online pharmacy is concerned.

**Aditya Khemka:** Also, on the U.S. side, Vinita, so you alluded to the fact that there the pricing is somewhat stabilizing in some products at least given the withdrawal by some of the incumbents. Can you help me understand, are there 2 ways of dealing with this, where in one case, you just take the one-off supply whatever your competitors are not supplying, and you supply that at a much higher price point? And the second, you're doing it as you sustainably gain that share. But then in that case, you don't get as higher price points. Are there 2 strategies here? And if yes, there are 2 strategies, which is the one that we have chosen for?

**Vinita Gupta:** So, we always go for the long term. That's what our partner customers usually want to go for as well. I mean, they don't want to be switching supply, especially for large volume products over and over again, that is a huge administrative cost at their end and the pharmacies. As a one-off, you can really get a good upside, typically we would do that only in situations where we don't have the capacity to dedicate long-term for this additional share gain. At that point in time, yes, strategically, we will leverage the opportunity and maximize. But otherwise, we typically try to build for the long term.

**Aditya Khemka:** And on the Solosec comment, Vinita, so we're already at a $5 million quarterly run rate of the branded business. And so could you just help us in terms of guidance on when do you expect Solosec to breakeven including front end infrastructure that you are having?

**Vinita Gupta:** We hope within the next 2 years, that we can breakeven. Our expectation from the standpoint of peak share revenue has not changed. We still believe that 15% share of that market is feasible, is doable. It's taking us a little bit longer, but in the next couple of years we aim to breakeven and hopefully, offset some of that near-term spend with an additional product and get to peak share in the next 4 to 5 years.

**Aditya Khemka:** One last question, if I may. So, you also participate in some of the tender businesses in emerging markets, Africa etc. Could you help me understand how the funding environment there has been? Has it improved versus earlier? Or has it been more or less similar?

**Naresh Gupta:** Yes, I think the funding has improved. And especially in the area of TB, there has been a conference in the United Nations, where all the countries have said that in the next 4-5 years, they want to eradicate TB from the entire world. As a result, as far as the funding is concerned, it has increased and there has been a lot of increase in the funding by the different governments in the world.

**Aditya Khemka:** So, would it be fair to say that given the improvement in funding and the aim to eradicate TB in the next few years, has the pricing for your products also improved?

**Naresh Gupta:** Well, I think the pricing in the tender business is very competitive, as you are aware, and there has been an issue of supplies also. So, pricing is not as attractive as in the normal trade business, but we are having a backward integration for TB etc. and we have been here for a long time. So, we continue in this business.

**Aditya Khemka:** I have one last one for you, Vinita. How much of our portfolio in the U.S. in terms of revenue, if you can, comes from plain vanilla oral solids?

**Vinita Gupta:** We have backward integrated so many of our products, none of them are vanilla that is what I would say. It is hard to really put a percentage on it. I would say there is still a good part of our portfolio where we are the market leaders. And I would say, as opposed to really commoditized

or non-commoditized from our perspective products where we have significant share, we have efficiencies and advantage from a cost perspective that makes us a good long term player.

**Aditya Khemka:** So, maybe it's more than 60% of your portfolio would be oral solids including Fortamet, Glumetza and the like?

**Vinita Gupta:** Yes, I would say so.

**Nilesh Gupta:** Yes, including the extended-release products.

**Aditya Khemka:** Including extended release, more than 60%.

**Moderator:** Thank you. We take the next question from the line of Anand Bhavnani from Unifi Capital. Please go ahead.

**Anand Bhavnani:** Just wanted to understand with respect to the FDA observation, what is the current situation and how long do you think we'll be able to resolve the issue?

**Nilesh Gupta:** So, we talked about this earlier of course. We feel good about where we are now. We have made significant progress with the FDA. We have been engaging with FDA as well. We've made significant progress in terms of addressing concerns that they would have. By the end of the calendar year, we should be able to offer 1 or 2 of these facilities for a re-inspection and we will see when FDA comes around for that. But if things go well, then hopefully, by the end of the fiscal, we should be able to turn 1 or 2 of these facilities around from regulatory status perspective.

**Anand Bhavnani:** So, sir, any comments on the U.S. growth that's happening and what the current status, how long that growth in the US market would get kind to resolve? And any financial implications that you would have to provision for?

**Vinita Gupta:** It's very early to comment on it, it was just a last couple of months. So, we are in the early stages of doing our own internal research, and we expect it to probably play out over the next couple of years. It is very early to comment on it. We believe from our standpoint, we stand in a very good position based on the internal work that we have done, but we will determine over the next quarters and obviously defend our position vigorously.

**Anand Bhavnani:** And ma'am lastly wanted to understand with respect to U.S. markets, while in the last few months, pricing has stabilized and there isn't much erosion. But are there any structural changes which the U.S. government can undertake, which can further lead to price erosion like for example, for the last few years, they have been speeding up US ANDA approvals and hence it's led to price erosion right from the growth generic. So, any other structural features of the U.S. market, which if they were to change that can impact us negatively?

**Vinita Gupta:** I think we have gone through our fair share of structural change in the U.S. over the last many years. And as a result of which, you have seen a number of generic companies exit. I would say any additional structural changes that the U.S. might make from a pricing standpoint probably will be a positive for the generic side of the business, meaning more conversion of the market into generics. There is more pressure, I would say, on high-priced brands in the U.S. at this point whether it is through government intervention, through additional price rebating or benchmarking price to other markets that is going to be more on the brand front.

**Management:** Thank you very much for your active participation, and we now look forward to seeing you again in the next quarter conference. Wish you all the best. Thank you once again.

**Moderator:** Thank you. Ladies and gentlemen, on behalf of Lupin Limited, that concludes today's conference. Thank you for joining us, and you may now disconnect your lines. Thank you.