



## “Lupin Limited Q4 FY2020 Earnings Conference Call”

**May 29, 2020**



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**Moderator:** Ladies and gentlemen, good day, and welcome to the Lupin Limited Quarter-IV and Financial Year 2020 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the opening remarks. 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 all.

**Dr. Kamal Sharma:** Thank you. Good afternoon, everyone. Welcome to this earnings call of Lupin. With me, I have Vinita Gupta, Nilesh Gupta, Ramesh Swaminathan, Arvind Bothra and Rajiv Pillai.

You already have the results in your hands, and you will see that this has been a good quarter. If you look sequentially, there has been a growth in sales. There has also been improvement in EBITDA margin by 5.3%. On a year-on-year basis also, the revenue line has gone up by 5.8%. Although at the EBITDA level, we are down by about 1.9%.

This has also been a year of settling a lot of overhangs, which had been there in our system. We are in a much stronger position to take the company ahead now.

In order to take you through the financial details, I will hand this over to Ramesh, and then we'll open the floor for question and answers. Thank you, and over to Ramesh.

**Ramesh Swaminathan:** Thank you, Dr. Sharma. And friends, it's good to be back, interacting with you all after a hiatus of 18 months. So very happy to be back with the Lupin family.

In terms of the financials, results are already with you, but let me take you through this again. Sales at Rs.3,791 crores for Q4as compared to Rs.3,716 crores for the previous quarter, which actually represents a 2% growth. It's flat as compared to Q4 of 2019. US, our most important market, grew 14% sequentially, US \$212 million as compared to US\$186 million in the previous quarter. Though, there has been a decline vis-à-vis Q4 of last year, and that you would recognize is essentially because of gRanexa. In terms of the full year, US sales were close to US\$800 million vis-à-vis us\$777 million in FY19, a growth of about 3%.India region saw a growth of 15% vis-à-vis Q4 of last year., You would also recognize that Q4 is always the weakest quarter in the year and that's why you see a decline sequentially. India region grew about 12.7%, on a full year basis EMEA, did very well. It grew 25.3% sequentially and 7% yoy. Growth was particularly strong in South Africa.

Gross margins for this quarter was 62.9% vis-à-vis 63.4%.in the previous quarter Friends, you would recognize that this is essentially a sales mix issue. In terms of the comparison with the previous year, it's down from 68.9%, essentially because last year we had a large component coming in from Ranolazine sales in the base itself.



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During this quarter there was favorable US dollar gains vis-à-vis the rupee, but unfortunately, it's been negated by Forex in South Africa and Brazil. In terms of EBITDA margins, we delivered improvement in operational profitability on a sequential basis, which is 19.4%, which is 530 basis points increase vis-à-vis the previous quarter. We closed the full year at an EBITDA margin of 18.7%, which is within the expected range of 18% to 20%. Sequentially it is higher because of lower R&D and sales promotion spends and also due to forex gains.

In terms of ETR, we've done fairly well. Though for the full year, it's still hovering around the 40% mark, but going forward we expect it to certainly go down. This is evident even in this particular quarter. For the full year next year, it should be around the mid 30's mark.

This year we did a lot of things in terms of the balance sheet restructuring. We undertook significant measures, in terms of optimizing our capital allocation and worked towards normalizing our ETR, which for various reasons has been higher than the standard. We divested our Japanese operations and undertook an impairment of the Gavis acquisition to strengthen our balance sheet. We believe that all of this would certainly result in better ratios over time. We used the divestiture of Kyowa to repay a large portion of the debt. The debt-equity ratio is favorable standing at around 0.12.

We're very well-positioned for better performance in the quarters to come. But for sure there is this overhang of COVID at least in the first quarter.

**Nilesh Gupta:** We can go ahead with questions now.

**Moderator:** Thank you very much. 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:** Congratulations on clearing many facilities in the last quarter. Just wanted to understand what's the update for the important facilities for Goa and Indore. Where are we in terms of submitting the CAPA plan and what is the estimation for the resolution?

**Nilesh Gupta:** As far as Goa is concerned, we completed our final update about 3- 4 months ago. As we had shared earlier, in March/April, we were going to go back to FDA for a reinspection. There are some additional enhancements that we've been implementing at the site. In the next couple of months, we plan to go back to FDA and be ready for a reinspection. Pithampur will follow very shortly after that. In Pithampur, there was a much more detailed implementation program called 'Quality First'. We have seen very good progress with that. I feel really good about it. We've still been sending updates. But I think in the next couple of months, Goa, and very shortly after that, Pithampur would be ready for reinspection. Probably even before Goa, Somerset would be ready for reinspection.



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- Prakash Agarwal:** So when you say a couple of months is it completion of the CAPA plan?
- Nilesh Gupta:** For Goa, we're done. Somerset, we have done as well. There are certain additional enhancements that we have been doing, which we would like to complete before we have interaction with the FDA. Again, in Pithampur, while we're done with the specifics, there are still certain additional works that we want to complete in the next 2-3 months before we go back.
- Prakash Agarwal:** So by the next couple of months we will be done with our entire work that we plan to do and request FDA for a reinspection?
- Nilesh Gupta:** Yes. In a phased manner, likely Somerset followed by Goa, and then Pithampur.
- Prakash Agarwal:** Understood. Fair enough. And my second question is on the US business. So we saw a good Q-on-Q improvement. I understand there could be some Levo impact, which would have improved. So would there have been any COVID-related stocking? If you could just highlight how is the movement, how much of it is sustainable and what is the expectation?
- Vinita Gupta:** We have some impact of COVID-related stocking in March, in particular, A big part of the ramp-up was levothyroxine as well. It went from 5% share in Q3 to 13% share in Q4. That ramp up is starting to show. We also had ramp up in other products. Some of the flu products ramped up, plus we had a couple of recent launches. We launched Vimovo AG in the quarter, that is a very nice launch for us. We recently launched Apriso AG as well, another good launch for us that will build into fiscal year'21. Some impact of Covid in March, and we are seeing some softness in April- May. So, we certainly will see some impact of COVID in Q1. But the COVID factor aside, we feel really good about our growth drivers for fiscal year'21, apart from levothyroxine, pretty solid base business. This business actually has been very stable through fiscal year'20, and we've seen very minor price erosion. We've been able to more than offset that in terms of volume. Combination of strong base business plus the Levo continued ramp up, some of the new product launches that we've had in the tail end of fiscal year'20 that will really build into fiscal year'21. We are very hopeful to get albuterol approval soon. We have had strong interaction with the agency, especially in the last couple of months and hope to bring it to market a little bit sooner than we had stated in the past. That should be another very good driver.
- Prakash Agarwal:** Any timelines you are attributing to albuterol approval this quarter, next quarter?
- Vinita Gupta:** Prakash, we had said that we would launch in the second half of the fiscal year. Hopefully, it will be a bit sooner.
- Moderator:** Thank you. The next question is from the line of Aditya Podar from BDT Financial. Please go ahead.



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- Aditya Podar:** I wanted to ask a question on ProAir. But you said that it's going to be launched a bit before the second half and the update for Goa and Indore will be given. I just wanted to know on the debt, what is the plan to bring down the debt? And any other non-core businesses or assets to be sold off?
- Ramesh Swaminathan:** The debt is down because we have repaid a huge chunk of it. Even after, the year end, we paid off another US\$267 million, which does not obviously reflect in the reported figures because that's as of 31st March. The debt-equity ratio stands at around 0.12x. There's something to be said about the fact that the overall working capital has gone up between December and March. We will do what it takes to bring it down to more acceptable levels over the next few quarters.
- Vinita Gupta:** And if I just add to it, we took a pretty hard look at all of our different subsidiaries and determined that we wanted to divest Japan. We don't have any other non-core assets at this point in time. We are very strongly focused on building not only our two major regions India and US, but also the other markets.
- Moderator:** Thank you. The next question is from the line of from Krishnendu Saha from Quantum Asset Management. Please go ahead.
- Krishnendu Saha:** With Japan out of the revenue stream in this quarter is this EBITDA margin the new norm, 19.4% with the other income and 14% without other income? And the second question is - in Japan is there any contract for us to supply anything for the next one or two years with them? And the third question is what could the effective tax rate this year and how do you see the EBITDA margin going ahead?
- Ramesh Swaminathan:** Well, several questions in the same breath. But I'll take the effective tax rate which was the third question that you asked. You would recognize this year has been close to about the 40% mark. But going forward, we have done a lot to restructure the business, and do what it takes to bring down the effective tax rate. We do believe that we will be closer to the mid-30s range and progressively it will certainly come down.
- Krishnendu Saha:** The EBITDA margin for the quarter, is this a base number we're looking at? Is this like, this is the number without Japan, right?
- Ramesh Swaminathan:** I will take that question. As you would recognize, the EBITDA margin is a function of several things. In terms of the realization that we have on products and the kind of measures that we take to contain the cost and the kind of R&D spend. We spoke about the fact that there is albuterol, which is a possibility during the course of this year, but we'll take that apart. Overall, EBITDA could certainly be between 19% and 20% range and this is without taking into account the COVID impact in the first quarter. As you would know, there are several moving parts out there across various geographies -India, for example, has been impacted in this particular month.



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For all practical purposes, we believe that it would indeed be the case when it comes to next month as well. There has been an increase in expenses because of trade costs going up. There could be some increases in raw material prices and this is something that's not been quantified as yet. There is, of course, the impact in the US itself, and Vinita will certainly take us to that story. It's going to be impacting our business in the first quarter, for sure. But if you would take that all apart and if we maintain kind of status quo, we do believe that there is certainly improvement going around between 19% to 20% and this is without taking into account the Forex impact.

**Krishnendu Saha:** Sure. And just on the Japan, do we have any contracts to supply anymore for the next period or so? Or this is just sort of business which is off completely?

**Nilesh Gupta:** As we had shared this in the past as well, there is a multi-year agreement to supply products that we were supplying out of India. In fact there are couple more products that are getting added to that as well and that part of the business will continue. It's smaller, but it will continue.

**Krishnendu Saha:** Nilesh, where would that line item be coming in from in the revenue item, where would we see it?

**Ramesh Swaminathan:** It is essentially phased. You're billing to Japan, to a third party. It is going to be coming in the other third party sales, albeit at a lower margin.

**Krishnendu Saha:** Okay. It will not be in APAC?

**Nilesh Gupta:** To answer that part, we would club that into the APAC number.

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

**Tushar Manudhane:** Just a clarity on albuterol. So are there any queries pending now with the USFDA?

**Vinita Gupta:** We responded to all the queries. And like I had mentioned, we've had some interactions with them in the last few weeks and have responded to all the queries.

**Tushar Manudhane:** That's great to know. And just on the R&D spend, we had this fourth quarter with 9.1%, so any outlook for FY '21?

**Ramesh Swaminathan:** The R&D spend should be kind of the same level as last year, about Rs.1,500 crore range on a full year basis.

**Tushar Manudhane:** And just lastly, any MR additions in the domestic formulation side this year?



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- Nilesh Gupta:** Yes. So pre-COVID, we had a plan to add a few hundred MRs. Some of them will still get added, because we spun out three divisions last year. In places where we feel that we don't want to fill up in the near term we'll see what to do. But there won't be material addition this year especially given that we have seen a slowdown in May, more so than in April. Obviously, we watch the spend lines very closely as we hope to see that growth coming back in India.
- Tushar Manudhane:** And just lastly on Levothyroxine, if you could just help us with the market share currently? And what kind of capacity utilization we stand at?
- Vinita Gupta:** The market share, as I mentioned, has ramped up from the 5% level in Q3 to double digit, to the 13% level in Q4. We are well positioned from a capacity standpoint to take 20%- 25% share, if we have the opportunity to do so.
- Moderator:** Thank you. The next question is from the line of Nithya Balasubramanian from Bernstein. Please go ahead.
- Nithya Balasubramanian:** So my first question is on your biosimilars pipeline progress. If you can update us on where you are on pegfilgrastim for the US and ranibizumab?
- Nilesh Gupta:** On pegfilgrastim, we are at a very good position. We just completed the PK study successfully. Now it's a question of ramping up the product and filing. Some of it will still take a little bit of time, but before the end of this fiscal, we expect to file, and then obviously we would look for a quick approval. We are very excited with the fact that we've been able to cross all the hurdles that were there in developing the product. On ranibizumab, we have started the India-centric trial and the plan is in Q3 to start a global clinical trial.
- Nithya Balasubramanian:** Okay. Are you planning on filing without a Phase III in peg?
- Nilesh Gupta:** I wouldn't be comfortable sharing our strategy. It is a complicated strategy as far as filing is concerned. But like I was saying, we have been able to complete whatever clinical development plans were required to be able to file the product.
- Nithya Balasubramanian:** Okay, understood. Thank you. And my second one was on Solosec, what sort of an impact have you seen, because of COVID. Obviously, clinics are shut and within acute therapy, we did notice a sharp downturn in the prescription share. Are you seeing that coming back up and do you see like the COVID impact has put a spanner in the work?
- Vinita Gupta:** Yes, there was a significant impact of COVID on the OTC specialty per se as well as on Solosec. We saw really the OB/GYN clinic visits come down to 20% level pre-COVID, and only for critical conditions. From Q3, we had started to see a good ramp up into Q4 in January, and in February we started to see the COVID impact, which impacted the scrips which we have seen



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down to almost 45% pre-COVID levels at the lowest. In the last 4 weeks we have started to see this stabilize. In April, we saw the scrip levels hit the bottom and since then we've seen it grow slowly. However, we have taken some significant measures to optimize that business. We had realized that Solosec is going to be a slower build, it had consistent growth but still at a slower level. Pre-COVID we just saw a strong reception to virtual calls, and doctor coverages through telehealth and taking virtual calls as opposed to the face-to-face interaction. We have really restructured our operating model going forward, to a higher level of virtual investment, and very significantly reduced our operating spend and burn rate nearly by 50%. We downsized the field team in the last couple of weeks to be able to really reduce that burn. So now having restructured the team, plus having the same focus on a different mix of virtual versus face-to-face interaction, starting to see scrip ramp up from the low of April. The recent wins that we had through the Solosec was put on preferred position by ESI couple of weeks ago. We also had very positive readout of trichomoniasis study to expand the use of Solosec. We feel pretty good about growing the business at a burn rate that we can sustain while Solosec grows.

**Nithya Balasubramanian:** If I may ask you a follow-up, now with the measures in place, when do you see your specialty business breaking even?

**Vinita Gupta:** Much sooner than what it was as of last quarter. It should be pretty soon, I would hope in fiscal year'22.

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

**Anubhav Aggarwal:** Vinita, one question on albuterol first. Just wanted to check, why is this product still in the shortage when IQVIA volume shows that now that shortage which was there is no longer there. Why is FDA still putting this under shortage item?

**Vinita Gupta:** The demand for albuterol went up significantly due to COVID. Being a rescue inhaler, we saw a significant jump, something like 30%, 40% through March as well as April. Since then it is stabilized, but still at a level well above the pre-COVID levels. Given the respiratory distress, as albuterol is a critical medicine required for treatment of COVID. The demand has gone up. From a supply perspective, we know that Perrigo launched in February but had very limited share so far. Cipla launched recently, but again stated that they're going to make product available over the next few months, We do think there is short supply.

**Anubhav Aggarwal:** So let's say what percentage of albuterol market is prescribed by physicians as a generic prescription right now. For example, Teva mentioned before that generics came in, that it was 40%. What would that number look like currently?

**Vinita Gupta:** Right now, I think generics are at over 60%.



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- Anubhav Aggarwal:** And just one question on famotidine also. I wanted to check how sticky is the volumes that we gained. Our product is a suspension product. Do you think there could be shift away to tablet or to let's say, move away to omeprazole at a certain point of time or this is what we called as very sticky right now?
- Vinita Gupta:** It seems like it is sticky, right now after the ranitidine issue. We saw a good amount of share move to famotidine, and obviously, we are in a very good position to leverage that.
- Anubhav Aggarwal:** But is it a supply shortage issue on that oral solid side, which is benefiting us, and once that is back we may have, I'm just thinking from a customer perspective, patient perspective, would the preference be higher for an oral molecule versus the suspension one or patient is indifferent? I'm saying on the famotidine side, is the patient indifferent between the oral form and suspension form?
- Vinita Gupta:** Maybe we can take this question offline. I don't have the mix of oral solid versus what it was prior to this ranitidine change and we'll take it offline.
- Anubhav Aggarwal:** Sure. And just my last question was on Solosec. I just wanted to check after the Express Script preferred supplier, will net pricing, which is a combination of the rebate to Express Scripts and the coupon strategy we have, will there in the short term net pricing be down and hopefully till the time volumes come up, can we see a dip in Solosec sales and ultimately getting the benefit out of it? Will it follow that kind of curve?
- Vinita Gupta:** Actually it's a very good question. The net pricing has actually improved quarter-on-quarter. Given the other measures we took, we ramped up Co-pay through the last six months. So that will itself have a positive impact on net pricing. And with Express Scripts now, the net price will increase even further.
- Anubhav Aggarwal:** Okay, so that co-pay is benefiting.
- Moderator:** Thank you. Next question is from the line of Neha Manpuria from JPMorgan. Please go ahead.
- Neha Manpuria:** Vinita on Solosec, I remember you mentioning in one of the calls that the cost for Solosec was somewhere around US\$12 to US\$13 million a quarter. Is that number right pre-COVID, so the 60% reduction that you mentioned is essentially on this \$50 million cost base. Is that the way to look at it?
- Vinita Gupta:** Yeah, roughly.



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- Neha Manpuria:** In that case, how should we look at leveraging this cost base? Because, we have been looking at in-licensing deals to leverage the cost that we have for Solosec. Do you think COVID slows our ability to augment our specialty portfolio in the US?
- Vinita Gupta:** Actually COVID potentially makes other opportunities available. But it really helps us get to breakeven sooner just on Solosec. We still have some of our legacy products like Methergine contribute to the top and bottom-line. Antara contributes to the top and bottom-line. We continue to look for opportunities. In fact, we are seeing more and more companies that are struggling through COVID and I would think they are having discussions about trying to find synergies.
- Neha Manpuria:** Specialty investment continues to be a priority for us in the medium term, that hasn't changed?
- Vinita Gupta:** Yes, it is. It is important to us. We just determined that Solosec is going to be a slow build, it makes sense to do it at a different operating burn.
- Neha Manpuria:** Understood. On the generic business in the US if we look beyond the Levo ramp up and albuterol, how should we look at the growth from that base because you'd have two large products in our base by then?
- Vinita Gupta:** Yes. Beyond that I think we have a very rich pipeline, Neha. Looking beyond fiscal year'21 we have on the inhalation front, Spiriva that we hope will get approved in this fiscal year, but will be launched in the next couple of years. We have other products that will come to market. Levo certainly will continue to be as a premium product going forward. Albuterol as well, is a material opportunity. Beyond that, we have Spiriva and other pipeline products coming in, we have also invested further into our inhalation pipeline. Recently with Fostair, we filed Dulera as well. We extended our pipeline. And then we have injectable products as well that we have filed, and multiple products to file.
- Neha Manpuria:** Understood. And my last question, on Fostair, what is the timeline for launch in Europe and how material can that opportunity be for us?
- Vinita Gupta:** So we intend to launch later this calendar year in Europe, third quarter fiscal.
- Neha Manpuria:** Okay. Would this be a pretty good launch? How material would this product be for us. I'm assuming, it will take some time to ramp up.
- Vinita Gupta:** That's right, it will take time to ramp up. It's not going to be overnight. But in the next 2 to 3 years, we look at it as a huge opportunity for our Europe business per se and our inhalation business in Europe.



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- Moderator:** Thank you. The next question is from the line of Hari Belawat from Techfin Consultant. Please go ahead.
- Hari Belawat:** This is regarding your financial results which are publishing every quarterly and yearly. This exceptional item is appearing for last many quarters continuously. And in fact, if we see FY20 and FY19, these are affecting on the bottom-line also. So what is this exceptional item particular impairment of intangible assets IP? If you can throw light on this please?
- Ramesh Swaminathan:** This has been appearing last couple of years. This year, for example, we made a huge profit when it comes to the sale of Kyowa itself. Apart from that, we had a loss when it comes to sale of KCC. Also took some provisions when it comes to Texas settlement that we had in America. On Gavis impairment we took a knock again. All of this actually comes in the full year results. Well it's exceptional, and that's why it's coming in at the line that it does and this is in line with the accounting principles.
- Hari Belawat:** I agree, sir. But like this IP is impairment of IPs. What is that other this investment we understand, profit or loss is okay, what happens to these IPs? We have acquired at certain cost and we are not using these IPs anymore so that you have provided in your accounting.
- Ramesh Swaminathan:** Yes. The reason is because that any asset that we purchase is supposed to be bringing in certain cash flows. If the cash flows are not in line with what we projected, there is obviously a need for an impairment of that particular carrying value, and that is what is reflected in terms of this impairment.
- Hari Belawat:** Actually, these exceptions have converted your bottom-line in red, FY20 and even FY19 also reduced. Anyway, if that is the practice, we accept it. The another one is discontinued operations you have shown a profit of 130 crore during this year, how is discontinued operations are giving profit to us, PAT?
- Ramesh Swaminathan:** It was actually a reclassification of the financials, the way the accounting standards warrant it. This is earmarked for our Japanese operations to the extent that it's not been continuing for the full year that is.
- Hari Belawat:** Anyway, these are all accounting practices, but they do serve a different picture of the company's performance overall. Just last question. Anything we are doing on for Corona drugs or vaccine. We are a big company; R&D expenditure also is very large. Any steps you're taken for any new drug or vaccine?
- Vinita Gupta:** We have multiple drugs that are relevant during COVID crisis-. There are two major ones, one that is short term is hydroxychloroquine, but the other that is azithromycin, has ramped up significantly. We have significant share of azithromycin, 40% share in the US market. We



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ramped up our supply significantly to serve the need through the COVID crisis. The other major drug from our existing portfolio is albuterol, as I mentioned earlier. The demand for albuterol went up significantly, but we are hoping to be able to get that approval and participate in the market soon with that product. Beyond that, we have explored our anti-microbials. We have pretty good pipeline of anti-infective, anti-viral products that are still being explored to see if any of that work for COVID.

- Hari Belawat:** And other things greatly during this FY21, I understand.
- Vinita Gupta:** Yes.
- Moderator:** Thank you. The next question is from the line of Vishal Manchanda from Nirmal Bang. Please go ahead.
- Vishal Manchanda:** Could you share CAPEX guidance for FY21 and FY22?
- Nilesh Gupta:** Last year's number was significantly low. It's going to be slightly more than last year's number. as we're adding capacities for certain sets of products and will remain similar for the next fiscal as well.
- Vishal Manchanda:** Right. So that includes the maintenance CAPEX. Is that right?
- Ramesh Swaminathan:** Yes.
- Vishal Manchanda:** And the depreciation expense was sharply lower on a quarter-over-quarter basis. So should we take this as the base number, going forward about 210 crores on a quarterly basis? Is that the right number to look at?
- Ramesh Swaminathan:** It's been reset because of the amortization, due to the impairment that we've taken on our intangibles. And of course, the business that we have sold and so on and it gets reset. Yes, going forward, this particular quarter would be indication of things to come.
- Vishal Manchanda:** Okay. And could you kind of call out the net Forex benefit during the quarter?
- Ramesh Swaminathan:** Yeah, it's close to about Rs.120 crores odd.
- Vishal Manchanda:** Okay, and just one final one. You have been talking about an approval for Fostair Inhaler in Europe. So is that due anytime now?
- Vinita Gupta:** Hopefully soon. We expect to launch it later in the year in Europe. But we are hoping to get approval in the next quarter.



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- Vishal Manchanda:** Would this be for the MDI version or the DPI version?
- Vinita Gupta:** For the MDI version.
- Vishal Manchanda:** And what is the sales for the MDI version in Europe?
- Vinita Gupta:** US\$500 million plus.
- Vishal Manchanda:** That's for the MDI version only?
- Vinita Gupta:** That's right.
- Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.
- Sameer Baisiwala:** Thanks. Good evening, everyone. And welcome back, Ramesh. So a few questions. On albuterol, if you were to get approval on the timelines that you mentioned over next year whatever 3 months, would you be having a staggered launch or do you think your supply chain is good enough for a full blown launch?
- Vinita Gupta:** We have been preparing well, Sameer for this launch. We will hope to maximize it.
- Sameer Baisiwala:** Okay, excellent. Vinita, on Solosec, for the new indication, trichomoniasis, is the drug presently being used for that indication off label? Or do you think getting the new indication approved would make or would give a good boost to sales?
- Vinita Gupta:** Hard to say, so there is a little bit off label for trichomoniasis, but obviously positive topline results and getting the label will make a material difference, to really try to expand the use of the product. At present, it's still a little bit away before we can get into the label, but our medical team, the MSLs will start working on it.
- Sameer Baisiwala:** And Vinita, missed you when you were talking about Spiriva, did you mention that you will get the approval in the current year?
- Vinita Gupta:** Yeah, we have a very strong file in place, and we hope to get the approval soon. I mean, of course, we can't launch for couple of years, but we hope to get approval this fiscal year.
- Sameer Baisiwala:** Great. So if I understand correctly, I think the key patent expires middle of 2022. So maybe that should be but what about the underlying IP court case?
- Vinita Gupta:** The court case continues



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- Sameer Baisiwala:** But how do you plan to take the IP part forward? I mean, would you hope for the full cycle?
- Vinita Gupta:** We'll see based on how it unfolds, what makes sense. It's a material opportunity for us, so we will determine what the best way to maximize it.
- Sameer Baisiwala:** Okay, excellent. And just one final one on complex injectable portfolio. Can you update us and you mentioned something which was not very clear? So how many filings have you done and these are for the substantive big products that you've been talking off in the past? And when do we start seeing the approval cycle?
- Vinita Gupta:** To date, we probably have 6 to 10 filings, if I'm not mistaken, not recalling that number for the past couple of years. We've not had any of the complex injectable filings as of yet, with the exception of Fosaprepitant, which continues to be a nice opportunity that we are trying to figure out how soon we can launch. On the Depot products, on Risperdal Consta, Paliperidone, we have made significant progress in the pipeline. It is still in the pipeline phase, but we have gone past proof-of-concept and have started working on the clinical study. So there is a good progress on that platform.
- Sameer Baisiwala:** And the filing for these products will be current fiscal or from next fiscal?
- Vinita Gupta:** No, the next fiscal. They will be going for clinical trials now this year, a little bit delayed also because of COVID.
- Moderator:** Thank you. The next question is from the line of Darshit Shah from Nirvana Capital. Please go ahead.
- Darshit Shah:** Sir, basically, I would like to know your assessment on the recent USFDA move to kind of recall Metformin extended release tablets. So what kind of impact do you see? I mean would it be a kind of normal batch recall for few of the companies? Or you probably think it might be a national recall like it happened in other products like Ranitidine and so?
- Nilesh Gupta:** Currently, we see it for certain batches, certain kinds of formulations as well. So it's still very piecemeal. We don't see it in an across the board issue for metformin.
- Darshit Shah:** And anything we heard from the USFDA for our products in this regard?
- Nilesh Gupta:** There is a discussion on one particular batch that we have been having with the FDA, which we would likely end up recalling.
- Moderator:** Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.



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- Surya Patra:** Just if you can update on what is the revenue number for the branded segment for this quarter? And I'll ask the subsequent question ma'am.
- Vinita Gupta:** Yeah, with similar levels last quarter around US\$4 million.
- Surya Patra:** Secondly, on the albuterol again. So, if I say that, this all three brands in the albuterol, those are interchangeable, then already for these three brands put together there are six players in the market. And we will be joining the market as seventh player and possibly there could be more competition going in. So generally I'm trying to assess that, okay what is your assessment about the competition in this space and the pricing scenario. And your aspiration out of this product opportunity in the US.
- Vinita Gupta:** We believe that right now the way to look at it is that you have the three brand companies, selling their AG's alongside the brands. And we have the first two true generic suppliers. But given the market conditions right now the way we look at it, it is a pretty attractive market from the pricing perspective. And we will be very prudent in how we go get share. We currently expect to get a fair share, a double-digit share and have planned the capacity accordingly.
- Surya Patra:** And about the kind of R&D spend or anything on the cost rationalization front going ahead because obviously, the kind of margin levels that we have been delivering or seeing since last sometimes. So, that always look bit suppressed like because of the kind of aggressive spending size with R&D. In the cost point, do you really see some improvement going ahead either because of some of the activities that may not be there going ahead. For example, your remediation expenses could be possibly getting to rationalize, or anything on the cost front that you can give us some indication with rationalization measures.
- Ramesh Swaminathan:** The endeavor is constant. It's actually a function of three things. The kind of products that we bring to the market, the kind of cost that you incur and of course the R&D expense and the like. I don't want to talk more about these products which anyway would happen over time. And we are, as you would know, geared up for a lot of things. We have our inhalations portfolio, we have biosimilars, we have specialty and complex injectables and the like, but all of those will happen over time. But one thing that's constant out there is, trying to read out the boundaries when it comes to, on the cost front. This is going to be across several lines. We've had a continuous engagement program with leading consultants working on several lines. We have a program to implement on the procurement front, which is really the raw materials, alternate vendors and the route synthesis and conversion. We are working on SG&A, the R&D expense front and for sure on the overall workforce itself. So we have actually seen some good results through the course of this year. It's not so visible to you because it's actually camouflaged in several parts. And there are several moving parts there itself, amongst lines. But as we unfold and as we go into the future, I would imagine there would be significant visibility on that, towards the end of the next fiscal, that is you would actually see a closing date which is certainly



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superior. But all of this, assuming that normalcy returns in terms of the business. As you would know, the first quarter would be impacted because of COVID across various parts of the globe. India, for sure, there are dark clouds. There are dark clouds in America. There is Forex fluctuation in the emerging markets. And business is down in other parts also. So those are again, something that we can't actually talk about, but in a general sense, you would expect that there is going to be tremendous focus on cost, and that would be contained.

**Nilesh Gupta:** Maybe if I can just add, one of the things that we've had is challenges. Some of the cost optimization we've done, there's actually a reduction in the realization as well, and that's why it's not getting reflected. But what Vinita shared as far as reducing the SG&A in the US on the specialty front that was part of the overall rationalization as well. And that will reflect on the numbers.

**Surya Patra:** Okay, just one more question on the taxes front. Ramesh sir, if you can just clarify this 30%, 33% kind of a guidance what you are giving for the current year, is it just because of that divestment of Japan that is resulting into?

**Ramesh Swaminathan:** No, we have done some significant restructure. We have taken issues upfront in terms of trying to bring down the losses in various subsidiaries, some tax planning in terms of the way we actually positioned or domiciled our IP. Then the kind of products coming in from various parts in terms of the overall footprint, in terms of the certain advantages of SEZs and the like. So all of this will bear fruit and that's why you would find a reduction in the ETR from 40% to much lower levels that I indicated.

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

**Nimish Mehta:** Most of the questions have been answered. Just one thought I would like to have from your side is, now that the lockdown related logistics issues are behind us. How do you see the migrant labors related issue impacting us and also in the industry, I mean, does it mean that the logistic issue will once again be a problem for us, and in that case, some smaller companies in Indian market may take over market? How do you see the situation?

**Nilesh Gupta:** I would say that the biggest problem with the logistics issue was the fact that courier companies had switched off. That was a big challenge. I think the bigger companies did better and going forward, I don't see the logistics issues as an issue. Even in the current status with the red zone, green zones, we are able to make product available adequately. The real challenge that we're seeing in India at this point of time is demand. Specifically, in May, we believe that the market, specifically for acute, has significantly de-grown. Chronic also, there is not increase because while doctors are starting to open up, there isn't adequate footfall. And I think May and June will go in that state of repair, and we really see the market taking off only after.



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- Nimish Mehta:** But because of the migrant labor going back to the homeland, we don't see any particular issue because of that. Is that a fair understanding?
- Nilesh Gupta:** Yes. Not specifically on that count.
- Moderator:** We take the last question from the line of Prakash Agrawal from Axis Capital. Please go ahead.
- Prakash Agrawal:** I had one clarification and one or two more questions. So one is on the press release you speak about your Florida inhalation facility inspection by US FDA, but done by UK MHRA. Can you clarify, would they come back when the things normalize or is it temporary EIR or how do we think about it?
- Vinita Gupta:** FDA inspected the site for Fostair that we have filed both from Coral Springs as well as Pithampur. We now have approval at both sites to manufacture Fostair, to have the flexibility from both sites that we wanted to build to be able to ramp up both albuterol and Fostair effectively.
- Nilesh Gupta:** Basically, FDA did it on behalf of MHRA, but it is permanent status of the site.
- Vinita Gupta:** And we are thinking of leveraging it for some government business in the US.
- Prakash Agrawal:** Understood. Thank you for that. And I missed your comment on Levo. So you mentioned your mid-teens now 13% to 15% and fiscal '21 you have expectation to go to 20%, 25%, is that right or 30%, 35%? I missed that.
- Vinita Gupta:** In terms of market share, 30%-35% would be a dream and it certainly would be tough to command a rational share perspective. But we would be very happy to get to 20% plus.
- Prakash Agrawal:** 20% plus, that's fair. And one more on metformin. So when FDA is talking about metformin and DMA issues, it captures even though the entire basket like the Glumetza of the world, including the Metformin generics?
- Nilesh Gupta:** Yes. So I think FDA has obviously been evaluating. So if the IR products, DR products like the fortamets, the Glumetzas, and yeah, there's a whole bunch of products, glucophage, so there's a whole bunch of products out there.
- Prakash Agrawal:** So it would be the entire basket. As of now, we have just heard or we are evaluating one recall is what you're seeing?
- Nilesh Gupta:** Yes.



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**Prakash Agrawal:** Okay, perfect. And last one from a demand perspective. What I understand is both India and US, because of obviously lockdown and patients not able to go to doctors, prescription levels have come down, but when you compare India and US which business is seeing more impact on volume would it be US or the India business?

**Nilesh Gupta:** In the US, while generics continues. And there is some pressure in specialty right now. In India on the branded generics right now, obviously the impact is more.

**Vinita Gupta:** Overall the US. prescriptions are down 20% even now, when we compare it to the baseline pre-COVID just because of many people have just not done doctor visits. So this is improving week after week but it is still 20% down overall.

**Prakash Agrawal:** As Nilesh said, India will be more, I understand because of the lockdown issue?

**Nilesh Gupta:** Yes. But in India, the good thing that we've seen is that in green zones, even in orange zones, there's a fair bit of returning back to normal as well. So, obviously, the India story is still panning out. But there are parts where normalcy is coming and particularly the red zones, which is also in some ways the bigger part of the market, which remains a big concern.

**Prakash Agrawal:** And the last one, like we have couple of licensing deals with AbbVie on the MALT1 inhibitor and going up with the MEK inhibitor. So is there any progress there and are we expecting any milestones in '21, '22?

**Nilesh Gupta:** Yes, as far as Boehringer Ingelheim deal is concerned, basis certain development we would expect a milestone in FY22. There are certain clinical developments which have to be done and they have been basically delayed by a quarter, thanks to COVID. On AbbVie also, there are a bunch of future milestones as well, but that one in particular is more in the overall AbbVie development portfolio. We feel very good about the compound. We believe that it will move ahead, but, there is an assimilation process internally before they take it forward.

**Moderator:** Thank you. I now hand the conference over to management for closing comments.

**Dr. Kamal Sharma:** Yeah. Thank you for connecting on the call and hope you had reasonable answers to all your questions. I look forward to seeing you next quarter and connect with you again for a chat. Thank you very much and all the best.

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