“Lupin Limited Q2 FY2021 Earnings Conference Call”

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MANAGEMENT:

- **DR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**
- **MS. VINITA GUPTA – CEO, LUPIN LIMITED**
- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
- **MR RAMESH SWAMINATHAN - EXECUTIVE DIRECTOR, GLOBAL CFO AND HEAD CORPORATE AFFAIRS, LUPIN LIMITED**
- **MR. VISHAL RATHI - VICE PRESIDENT, CORPORATE FINANCE**
- **MR. ARVIND BOTHRA – HEAD, INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**

Moderator: Hello, welcome to Lupin Q2 FY21 earnings call. Please note, 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 raise your hand from participant's tab on your screen. Please note that this conference is being recorded. I now hand over the conference over to Lupin management. Thank you and over to you Sir.

Kamal Sharma: Thank you, Aditya. Good evening friends, this is Kamal Sharma and I welcome you to the earnings call for Q2. I have with me Vinita Gupta, Nilesh Gupta, Ramesh Swaminathan, Arvind Bothra and Vishal Rathi. As you would have seen from the results, we have had a relatively good quarter where you see growth of 9% QoQ in the revenue line and a growth of 14.1% in the EBITDA line. Also, the profit before tax has grown by 32% sequentially. On YoY basis, the revenue and the EBITDA (before forex & other income) have been more or less flat. In this quarter, it is heartening to see is that there has been growth all around in all our geographies. Just to walk you through all the financial details, I will now request Ramesh to take that up and thereafter the floor will be open for you to ask any questions. Thank you very much and over to you, Ramesh.

Ramesh Swaminathan: Thank you, Dr Sharma. Friends, welcome to a good set of numbers as compared to our recent past. This quarter, we saw a rebound in several ways. Sales for Q2, were Rs.3,781 crores compared to Rs.3,468 crores in Q1, a growth of 9% QoQ, and 1% decline over the same period last year. However, you should also remember that last year, we had an NCE licensing income. If you were to knock that off, sales were actually up by 2.9% YoY. US sales grew by 15% sequentially to US$ 180 mn vis-a-vis USD 157 mn in Q1. The reasons for the growth were essentially launch of Albuterol coupled with inline generics going up in Q2. The India Region saw a 0.7% YoY decline due to COVID impact on demand, especially for acute products. We are seeing growth in the market now and expect Q3 to be much better than Q2. Degrowth in the acute products sharply reduced in Q2 as compared to Q1. We continue to outperform the market in focussed chronic therapy areas, as in the case of anti-diabetic and cardiac In H2, we expect to grow by 6% to 8% overall. API sales continues to show strong growth of 22.5% YoY due to improved pricing as well as favourable forex as compared to Q2 of last year. API sales were down 8.6% QoQ due to low volumes on some of our key products. We have seen price stabilized at Q1 levels. Sales for EMEA grew by 30.4% QoQ due to pick-up in demand in all markets as well as the launch of Etanercept in Germany through our partner, Mylan. Sales of Growth Markets grew by 8.1% QoQ due to pick-up in demand in most markets led by Mexico and Philippines. Coming up to the gross margins, gross margins were up at 63.5% as compared to 62.9% in the previous quarter. This is coming from an overall business mix improvement led by America, slight moderation on the freight rates and of course the fruits of continuous improvement programs that we have been pursuing for the last several quarters. There is no significant impact of forex in Q2 vis-a-vis Q1. One

very important development during this quarter was on the employee benefit line. In Q2, we closed at Rs.685 crores, vis-a-vis Rs.793 crores in Q1, a reduction of well over Rs.100 crores. This is led by the specialty restructuring we did in the last quarter plus there were some COVID linked incentives. We took a lot of steps to contain the overall costs and the benefits are there for you to see in Q2. We expect this to continue, though we do believe that Q3 would be slightly higher led by increments, which would be declared. Manufacturing and other expenses in Q2 was Rs.1186 crores as compared to Rs.958 crores, essentially driven by forex losses, higher R&D spends and. sales promotion expenses. There are also certain one-time costs contained in here. We believe that our focus on SG&A expenses will continue, and you will see this bearing fruit and operating leverage really clicking in Q3 and Q4. In terms of ETR, we have taken a number of steps, as could be seen in the results itself, there has been tremendous improvement. The full year ETR we believe would be in the mid-30s. If you look at the EBITDA margins, which is the most important thing, we believe that we have delivered tremendously on our promises. The reasons for that are covered in the gross margin's explanation, as well as the improvement that we saw on the manpower line We believe - that we would deliver on the promises we made. If you'd recall, we guided for 19% to 20% in the beginning of this year. But I also said that because of COVID things are a little fluid. We now strongly believe that going forward there would be a tremendous improvement in EBITDA and perhaps you will see Q4 at around 18.5% and overtime we will be back to the 20% - 22% level that we were always known for in the past. With this, we open the floor for Q&A session.

Moderator: Thank you very much, Sir. We will now begin the question and answer session. Anyone who wishes to ask questions may raise your hand from participant tab on your screen. Participants are requested to use their headphone or earphone while asking a question. Before asking a question, please introduce yourselves and requesting you all to limit your questions to two at a time to provide others an opportunity. You may get back on the queue.

I will first request Nikhil Mathur to ask your question.

Nikhil Mathur: Hi, Good evening everyone. The first question is on the other expense line. If I look at other expense that has been recorded this particular quarter, they are broadly in line with what it was pre COVID on a quarter to quarter basis, whereas what we have seen in certain other peer set of yours is that the other expenses line has seen quite a bit of rationalization, especially in this COVID environment. Can you throw some light why there's some divergence between what's happening in Lupin and possibly some of the other companies out there?

Ramesh Swaminathan: I answered this at the outset itself. There was a higher component of R&D expenses. There's also normalization when it comes to field operations in India and other parts. There are certain one-off items which are contained in here. There's a partnered product in America, and there's an element of that. All of this is contained in this line**.**

Nikhil Mathur: Okay**.** Does this line item still have certain remediation costs for the plants, which are still to be inspected? Or that is completely over now?

Ramesh Swaminathan: A large chunk of that is more or less done. We are now waiting for the inspection to happen.

Nikhil Mathur: Okay. Another question is on the US part of the business. Now, I imagine that Glumetza was launched sometime towards the end of the quarter, Albuterol also

came in towards the end of August/1st week of September. So, isn't it, the way it functions is that you might have shipped inventories, say for a couple of months, or one month, or even three months for that matter, and the numbers could have been a bit better than what have been recorded or the inventories that have been shipped for Albuterol or for Metformin are pretty much taken care of them the month in which they have been launched.

Vinita Gupta: Yeah, so it was at the tail end of August and September. We're ramping up our supply of Albuterol, and not really supplying a couple of months' worth of inventory, like a typical launch. We continue to supply additional product in Q3 and expect that by Q4 we will be at a very good level with Albuterol supply. So, no multiple months' worth of revenues that you see in this quarter. Likewise, in Glumetza generic relaunch, we're very pleased to relaunch in September as we promised and have been able to gain share. There was a disruption in the marketplace at the time that we relaunched, much like when we had to recall the product and we are again ramping up share there.

Nikhil Mathur: Okay, Thank You.

Moderator: Thank you. The next question is from Nithya Balasubramanian.

Nithya Balasubramanian: Yeah, hello. Thank you. So, a couple of questions on the US business. Last quarter, you had mentioned that the flu products didn't perform well. Can you update us on whether that's picking up in sales? Is that reflected in Q2 or not yet?

Vinita Gupta: Actually, Q2 was the lightest from a flu products' standpoint, Nithya. It tends to be the lightest, just given the seasonality. We haven't really seen the flu season kick-off in a major way, we are tracking that very carefully. Hoping that in Q3, we're going to see an upside from the flu products. I'd say all of the anti-infectives, Tamiflu and the Cephalosporins, Azithromycin, all were down versus Q1. But the other inline products had a very strong performance and then the addition of Albuterol, as well as relaunch of Glumetza helped us grow in Q2.

Nithya Balasubramanian: Albuterol, if you can tell us a little bit about what the pricing environment is looking like and can you give us some colour on your market share, since you've been able to launch the product.

Vinita Gupta: It's very early days and as I mentioned that we are ramping up supply of the product to meet the demand. We see a very strong demand at this point in time, in particular, given the changes in the marketplace with Perrigo having recalled their product. There certainly is a demand and supply gap at present. Our team is working very hard to meet the demand as much as we can and the pricing is holding up, as you can imagine again given that Perrigo is out of the market. We are the only true generic now to ProAir on the market and the pricing is holding up.

Nithya Balasubramanian: You can share with us what is the discount level compared to the brand pricing prevailing?

Vinita Gupta: I wouldn't want to comment on pricing.

Nithya Balasubramanian: Fair enough. Just a last one on the manufacturing and other expenses. So, Ramesh you had mentioned that there are some one-time costs in the number. If you can help quantify what that is and so that we can understand what would be the new level?

Ramesh Swaminathan: It's not a very significant amount. It's about Rs.10 -.15 crores. We can also take it offline.

Nithya Balasubramanian: Thank you.

Moderator: Thank you. Participants are requested to introduce themselves and their firm before asking their questions. Next question is from Neha Manpuria.

Neha Manpuria: Thank you for taking my question. This is Neha from JPMorgan. I have two questions. First on the India business. Given our strong presence in chronic and our opening remarks about our performance in chronic, could you explain the reason for the muted growth that we witnessed in the India market or some colour there? And a follow up question on India? Ramesh, did you mention 6% to 8% growth for the second half of FY21?

Nilesh Gupta: Okay, maybe I can take the first part**.** You're right, compared to our peers set, the proportion of sales that we get from chronic is perhaps the highest. We've had strong sequential growth, the year on year growth is flat. The chronic part is actually done fine. For acute, even sequentially we only had 2% growth. On the acute side, our feeling is that the bigger brands have done better. Other than that, people who don't have a very large acute portfolios such as ours, have not fared well in this market. Like Ramesh shared, we believe that the market is bouncing back and it certainly has in September and October. We see, probably in the second half, market growing 4% to 5% YoY and, and on that backbone, we believe that we will grow 6% to 8% in H2FY21.

Neha Manpuria: Understood. My second question is on the operating margin guidance that you mentioned, 18.5% by fourth quarter, could you just highlight some moving parts on what would get us there? Because you seem to indicate a higher employee cost, other expenses, I understand, again R&D remains a moving factor. So, what essentially would be the key driver to take it to, the 18.5% in the fourth quarter, and I'm assuming this includes other income.

Ramesh Swaminathan: Neha, as you would recognize, it's a function of several things. Firstly, on the products front, we'll have the full measure of Albuterol coming in and its flu season. So obviously, America would perform much better with Tamiflu and a host of other products as well, Cepholosporins and the like. We expect normalization on the freight front as well. There's continuous improvement on the various initiatives on the gross margins. We think that gross margins would tend to be a little higher than what it is today. When you come to the manpower cost, whilst I said that there will be a slight increase in Q3, and that will sustain in Q4, it's just that, it's coming out of increments. we don't expect a radical shift. It will be Rs.10 crores odd to speak it will not be huge. And there's a tremendous focus on cost, especially when it comes to sales and promotion expenses and the like. So, all of this will certainly bear fruit and we think that we should be a programmed for something about 18.5% as a run rate going forward for Q4.

Vinita Gupta: Also, on the manpower cost, just to put into perspective, we've been able to reduce it to 18% of net sales and should be able to sustain that going forward.

Neha Manpuria: Understood, thank you so much.

Moderator: Thank you. Next question is from Kunal Dhamesha.

Kunal Dhamesha: Hi, this is Kunal from Emkay Global. The first question is, again, on the EBITDA margin guidance of around 18.5%. What kind of flu season have you built-in? Have you built-in similar to what you have seen in the last two years? Is that the right or fair assumption to make in your guidance of 18.5% margin?

Vinita Gupta: Actually, the major driver there is Albuterol ramp up and other product launches as well as flu season products kicking in. We are assuming that the flu season is a little bit late, but given the Albuterol ramp up, plus the inline products ramp up - we're still in the process of ramping up Levothyroxine. We have other new product launches in this quarter as well as next quarter. We have Tacrolimus, Mycophenolate, Posaconazole, Dimethyl Fumarate, that we're planning to launch shortly in the next couple of weeks. So, it's a combination of all of those, including some increase in the flu season products.

Kunal Dhamesha: Okay, thank you. And, again, I wanted an update on the status of Spiriva in terms of any date that we got, and when does the 30 months stay expire? Have we heard anything from the FDA, on that product?

Vinita Gupta: We are in constant dialogue with the FDA on the product and on track with all of the reviews from the agency. The product launch date is not until June- 2022. So, we feel pretty good to be able to get approval in time. We're hearing that so far there has been no other company that has made progress on the development front. So, feel pretty good about our position.

Kunal Dhamesha: Okay, thank you.

Moderator: Thank you. Next question is from Damayanti Kerai

Damayanti Kerai: First clarification on the staff cost front. So, Ramesh, you mentioned in your opening remarks that large part of the decrease which we have seen in second quarter was due to restructuring in the speciality business. So, I assume that It is related to Solosec front and it should be structural change, right?

Ramesh Swaminathan: We also had done some expenditure reduction in past like Brazil and the like. There was also some income coming in because of the CARES act in America. All of this actually brought the staff cost to the levels that are there. As I said, it could bounce back slightly, but as Vinita pointed out, we would still be at 200 basis points reduction vis-a-vis the previous year.

Damayanti Kerai: Okay, so Q2 broadly served with base going forward with some increment in line with business growth rate, Right?

Ramesh Swaminathan: Business growth and of course increments should be accounted for normalization of that and so on.

Damayanti Kerai: Okay, thanks for that. And my second question is on your injectables portfolio. You always mentioned that it will be one of the critical growth drivers for your US business. So, if you can share some update and how do you see this part of the business shaping up in next three to four years from now?

Vinita Gupta: Sure, we made tremendous progress on the injectables portfolio. I'd say from a business growth driver within the next three years. Right now, the inhalation products will really drive the next year or two. The injectable products will also start. We are focused around four areas- iron products, peptides, Depot injectables out of

Netherlands and partnered products, in particular, the liposomal products that we licensed from ForDoz. We have made progress across each of these areas in the last couple of months and quarters. We expect to launch first, one of our peptide products, Ganirelix, in particular, that we are getting ready to file this fiscal year. We would hope that it is launched in the next fiscal year. And then our iron products will follow that and then both the Nanomi Depot products paliperidone and Risperidone as well as the liposomal products doxorubicin and Ambisome will be in. So, that's roughly the evolution from a launch perspective. On the injectable side, there is good synergy with biosimilars. We have the Pegfilgrastim product that is progressing very well in development. We hope to file that later this fiscal year and the commercial strength that we have started to build on the institutional front is something that we leverage across both biosimilars as well as injectables. So, I'd say in the next two years, really the peptide products plus Pegfilgrastim will start contributing.

Damayanti Kerai: Sure, thanks for your explanation. So, what I understand in near term, it will be more on the portfolio build-up and any sales, which we should expect meaningfully coming to our numbers should be starting most likely after a FY23-24 timeline, right?

Vinita Gupta: Yeah, that's right**.**

Damayanti Kerai: Okay, if I may just squeeze in one more? Can you just provide update on biosimilar Enbrel launch in the Europe? So, which all other countries you will be targeting in near term after Germany? Have you launched in any other market other than Germany?

Vinita Gupta: Yeah, it has been launched in October-2020 in Finland and Croatia. And in the next couple of months, this fiscal year, we expect to see the product launched in France and Belgium as well. So, there is a full plan to launch it across all of the key markets.

Damayanti Kerai: Thanks for the opportunity

Moderator: Thank you. Next question is from Prakash Agarwal**.**

Prakash Agarwal: Yeah. Hi. This is Prakash Agarwal**.** Good evening and Good morning**.** My question is on Somerset. I understand that the inspection is done. If at all, you can confirm that, and do we expect the resolution of OAI or what is our current understanding if you can comment there?

Vinita Gupta: Prakash, the inspection is not done. It is still ongoing. So, we will not speculate. It's been a longer inspection given the fact that, through COVID it's been a little bit of a challenge. We had a COVID case, which led to a hiatus of two weeks. But we're very pleased that through this challenging time, the FDA has made time to come and inspect our facility, and we'll hope for a positive resolution.

Prakash Agarwal: Perfect all the best for that. Secondly, on the US, if I heard that correct, you're expecting a ramp up more so from Q4 on Albuterol not the current quarter when it's really in a sweet spot given Perrigo's withdrawal. So, what is the key bottleneck in terms of ramping up? Is it, the compound I think you had enough time to prepare that, is it the bottling or what really goes into that it takes time and also seen from your you know, the other competitor Cipla also took time? So, is it product related? Or is it like other vendor related? If you could help us and that's why you think Q4 would be more appropriate in terms of ramping up.

Vinita Gupta: We hope to at least be working towards doing more also in this quarter. So, you will see a little bit of a ramp up, but we'd like to be at a different level with the product just given the demand, the current market situation, and that we expect to meet really in Q4. It is a complex supply chain especially with third party vendors on the components for the device and the lead time is a little bit longer. Our team has been working very hard to ramp up and, we will see some benefit of that in Q3 as well.

Prakash Agarwal: Okay, perfect. And lastly on levothyroxine. So, understanding your commentary, you've talked about ramp up, but if we see the market share in Bloomberg, primary market share has been more or less stable or very marginally up. So, we had this all the RLDs in place and the expectation that it would move up. And why we still think that it will continue to move up, and what is the current bottleneck?

Vinita Gupta: Yeah, so we have grown our share a little bit, by a couple of percentage points, If you look at the share in terms of generic share, we have 16% share at this point in time. The reason I say we expect to ramp up is that we believe there is really more of a potential even with our existing customers to get additional pull through versus their forecasted demand, and what the demand has been. We're working closely with them to try to maximize that. We're not done yet and still working on gaining additional share on the product and continue to work towards it. But in the near term, we see the potential of really growing share, just like we've grown in the last month, the last couple of months, we picked up really some small accounts, that added to a couple of percentage points. In the next couple of months, we expect really to have better pull through with the existing customers itself.

Prakash Agarwal: Thanks. Perfect, I have one more question, but I'll join back. Thank you.

Moderator: Thank you. Next question is from Shyam Srinivasan.

Shyam Srinivasan: Hi, this is Shyam from Goldman Sachs. Thank you for taking my questions. First one on the presentation, you talked about a quality action plan launched in July 2020 on the regulatory side, so what is this, and if you can give us some kind of what are the things that we are trying to achieve through this.

Nilesh Gupta: The global quality action plan is really an overall transformative plan to address quality actions that come out anywhere. So, it could come from an FDA inspection, it could come from any other inspection, it could come from an internal audit. The idea really is, how are we implementing corrective plans globally. It's basically a broader, deeper transformation being driven across the company and also ensuring that any actions that we take are assessed, and addressed across the company, across all our sites. It covers every part of the quality system. It's just something that we believe, comprehensively addresses any issues that agency or any other body finds out, or that we feel that we need to address as well. This is something that we had planned to launch last year, it was deferred. We finally launched it in July, and it's something which is very rapid. The idea is what are all the pending issues, for example, one of the sets of issues that we had was investigations. What are the actions around investigations? How is it being addressed across the company? Making sure that all sites rise to exactly that same level across. So, an overall management tool, as well.

Shyam Srinivasan: Thank you. Well, just some follow up on that. The presentation also talks about desktop audits have been done at Dabhasa and Pithampur, and just some of the learnings that we've seen of that and trying to tie it to Ramesh's point that FDA may not be doing, desktop audit. So, you can just reconcile that.

Nilesh Gupta: We've had other regulatory agencies like TGA, do desktop audits. It depends on the inspector; it depends on the agency as well. We've seen some people do a much more virtual kind of interactio, some people happy with just more of a document kind of review. As you know, the USFDA does not have an approach aligned for remote kind of inspection. There have been document requests, we've had a couple as well, a lot of other companies have had as well. I think those go more in the line of PAIs, for facilities that are otherwise already compliant or even for new facilities, for that matter. So, it's a little bit all over the place. Some of the regulatory bodies are just choosing to extend GMP certifications, some of the others are choosing remote interactions as well. We personally felt that the remote interaction was extremely effective. Like Vinita said we will we love to see how we can engage with USFDA, to move some of our OAI or warning letter facilities ahead.

Shyam Srinivasan: Last question is on the top line guidance if there is any, I know you've talked about India growing second half. But if you could at least qualitatively tell us how should we look at the rest of the businesses including growth markets API, some sense on the top line? Thank you.

Ramesh Swaminathan: As I was saying, things are normalizing across various markets. If you look at America, it hit USD 180 mn, but we think going forward, it will be in the vicinity of slightly more. Q3 and Q4 would certainly be growing on Q2 base. If you look at India, as we said, we expect Q3 and Q4 growth to be certainly much better. If you look at the emerging markets, Philippines is still a little under the water because there seems to be a bit of a recession out there. But Australia, Mexico and Brazil, all normalizing very fast. Europe performed particularly very well in Q2. We expect that momentum to be sustained across Europe as well as South Africa. We have Etanercept, we have NaMuscla ramping up. So, we do expect our overall growth rates to be in line with the respective regions potential. But certainly, upward of 10%, for the company as a whole in second half.

Shyam Srinivasan: Thank you and all the best.

Moderator: The next question is from Girish Bakhru.

Girish Bakhru: Hi, this is Girish from Bank of America. Vinita, one question on Albuterol. So, is it fair to, kind of, understand that Perrigo exit right now has benefited you and Teva as we see from the data?

Vinita Gupta: Yes.

Girish Bakhru: I'm just looking at the units that Perrigo would have vacated, let's say 7- 8 mn units. And if I just do the back-run calculation, would your current capacity be largely absorbed in meeting the market that you would have got from this opportunity?

Vinita Gupta: We are ramping up our supply as I mentioned. We are selling as much as we can make at present.

Girish Bakhru: And when you say that it will gradually ramp up. I mean, would it be like, when if you could give a quantitatively, would it be potentially a million unit plus kind of a product? Can we look at those numbers?

Vinita Gupta: Yeah, certainly from Q4, we are targeting that, from a capacity standpoint, we will be well above the million unit per month.

Girish Bakhru: Okay, that's helpful. and just on this overall second wave I mean, broadly, there's a consensus emerging that maybe there is a big winter wave. So, could one also see another instance of Albuterol demand supply mismatch, as we saw in the first phase of COVID.

Vinita Gupta: We are tracking it very closely. It's actually a third wave if you look at, and it's worse than the first and second wave. We're seeing similar level of hospitalization. So, there could potentially be an increase in demand over the next few months.

Girish Bakhru: And this is not built in the 18.5% exit margin guidance, right?

Vinita Gupta: No, Albuterol is built in.

Girish Bakhru: When a potential of let's say, Albuterol, doing exceedingly well in Q4.

Vinita Gupta: There is potential upside on Albuterol.

Girish Bakhru: Thank you.

Moderator: Thank you. Next question is from Sameer Baisiwala.

Sameer Baisiwala: Thank you. Good evening, everyone. So, a couple of questions. First of all, Ramesh, on the EBITDA margins, I think you've made an opening remark that beyond 18.5%, you're looking at 22%. Can you just clarify that and the timeframe and the drivers for that?

Ramesh Swaminathan: Yeah, I was saying that 20% - 22% is where we were, in the not too distant past, so we should be getting there. We are moving in that direction because of the various steps that we are taking We spoke about products, we spoke about focus on gross margin improvement, on manpower and a host of other things also. We think that we should be there in the next few quarters. It's not for this year, for sure, but we are hoping to get there as early as possible.

Sameer Baisiwala: Great, thanks. The second question is on Fostair. Vinita, can you update us on the approval and launch timelines?

Vinita Gupta: We've had communication with the MHRA on the product and expect approval in the next quarter.

Sameer Baisiwala: Okay, great, thanks. Just one or two more if I may? One is on Solosec. Vinita, on reviewing and what's your expectation on ramp up, I remember, our aspirational volume market share used to be 15%, so any updated thoughts on that? And second, also very quickly on US pricing environment, is it better YoY but not better QoQ, is that the way you think about it.

Vinita Gupta: On the pricing it's pretty stable at this point, as we look at it on QoQ. For the last couple of quarters, it's fairly stable in the mid-single digit kind of erosion, if you compare it to last year. As far as Solosec goes, the last two quarters have been quite a dynamic situation on that business. One, because of COVID itself the business was down 50% and then with the restructuring, bringing the sales force down from 120 plus people to 45 people in June, certainly had an impact on our share of voice. So, if you look at it, Q2 versus Q1, our scrips are relatively flat, and revenues also relatively flat. Obviously, that's not what we are satisfied with. The team is working on ramping up the scrips and revenues. There is a strong focus around the managed-care wins that we have had, more targeted pull through efforts around the territories and

physicians with the managed care wins. And second, we are also working to increase our share of voice mean. Given the drop in the Salesforce, as well as share of our voice, and the product being very promotion sensitive, we are working on non-face-to-face, a digital complement to our face-to-face interaction to increase our share of voice. And third, one of the near-term major opportunities that we have is the trichomoniasis indication that we filed for this past quarter in August. We would expect that indication to be approved by June or so next year and that is another opportunity for us to reposition Solosec. We are hoping that the COVID impact is going to be minimized by then, because COVID is still impacting the calls in the OBGYN offices. Our calls are right now ~35% face to face. 65% are still virtual calls. So, we're hoping that also will improve. As we get into, Q4'FY21, , i.e. going into the first quarter of next calendar year, we hope to be optimized from a share of voice standpoint, as well as a targeting standpoint to be able to leverage that BV as well as trich into June next year.

Sameer Baisiwala: Thanks a lot, Vinita. Just to complete the point on Solosesc, if my understanding is correct, this is a bit of a recurring situation from the patient's point of view and if that's correct, are you seeing the renewal or the reuse by the same patient. Are you tracking that data?

Vinita Gupta: We are seeing some of it. Right now., it's been a little bit disruptive because of the surges in the different states. The call activity in a particular office has not been at the same kind of level, as one would expect. It's not an optimal level of promotion, I would say. But we are seeing some patients, that are dealing with recurrent BV, taking the product over a period of time as opposed to an acute care like, we would hope for more of that. But right now, a majority of our business is coming from the one-time use.

Sameer Baisiwala: Great, thank you so much.

Moderator: Thank you. Next question is from Nithya Balasubramanian.

Nithya Balasubramanian: Yeah. Hi. So, I had a question on the India manufacturing plants that still have a warning letter or an OAI status. So, Vinita, I think in one of the earlier earnings calls you mentioned that this year, you might launch 15 less products, if the warning letter status is not lifted. Now we're actually talking about FY'22 and we still haven't unfortunately, because of COVID, inspections haven't happened. So, assuming that gets delayed, what are the number of launches you would have normally expected for FY'22, from these plants that you'd like to get into?

Vinita Gupta: We have an impact of the products that are held back because of the OAI and warning letter. We don't have clarity as of yet, but I can't imagine that the FDA does not do anything about these product approvals over the next couple of quarters. One would expect that the agency is not going to start travel anytime soon. certainly not, until the vaccine is out there and very widely used, that they're going to see FDA inspectors travel back again. So, we do think there will be some solution over the next couple of quarters. I do want to say, though, we certainly would like to see the full impact of all of our pipeline products. But, as we look at the growth in the near term that we talked about, as well as we look at growth in the next year, it's very much from products that we either have approval for or are from other sites that have been inspected and cleared.

Nithya Balasubramanian: So, you're hopeful that there will be a resolution in the next couple of quarters.

Vinita Gupta: We hope that the FDA is going to come up with a solution.

Nithya Balasubramanian: Okay. All right, just one more on the complex injectables portfolio that you're building. Any visibility on when you're likely to file the complex Depot injections for the paliperidone and Risperidone? Can you give us an update?

Vinita Gupta: We have made good progress there. We are entering into the clinic with the two programs next quarter. Just given the length of the studies, it will take us through most of next year. So, the filings would really be calendar year 2022.

Nithya Balasubramanian: One of your peers mentioned that FDA is now expecting you to submit impurity data through the course of the shelf life and asking you to compare it to the reference drug. Is that now an expectation for all of these complex injectables?

Vinita Gupta: We haven't come across that as of yet. But we'll make a note of that.

Nithya Balasubramanian: Okay. All right. Thank you.

Moderator: Okay, next question is from Surya Patra.

Surya Patra: Yes. So, thanks for this opportunity. Just wanted to have some sense on the flu season in US this year. There are industry data points, which suggest a kind of robust flu season, given the COVID background. What is your understanding? And what is your preparedness for the flu as one of the leading suppliers of the flu product for the US market.

Vinita Gupta: The flu season is a little bit late, as we see it, right. We starting to see some ramp up, through October, we've seen some ramp up but, tracking that very carefully. I would expect to see more within November and December and we are fully prepared to leverage the opportunity as we have been in last years.

Surya Patra: But is it right to believe that given the COVID background the kind of intensity of the season will be much stronger because certain data points suggest 40- 50% kind of YoY growth.

Vinita Gupta: We haven't seen that in the ramp up of cases so far and showing up into in the demand from a prescription standpoint, but we are tracking that very closely. Typically, there are some years we have seen the flu season come in pretty late in the year even through December sometimes. So, we are tracking that very closely.

Surya Patra: Now on the Glumetza, if you can give some sense having seen whatever has happened for the product in the US market. So, with that relaunch, what is the competitive positioning and the kind of quantum of opportunity that we should be seeing out of it?

Vinita Gupta: Actually, we are very pleased with the relaunch. One that we were able to do it in September, when we had planned and promised to, and two - the time that we relaunched in September, there was more disruption in the marketplace. We were able to gain back our share of 50% plus. That will, of course show in the next couple quarters in terms of gain in revenues. We've been happy with the share gain in terms of the customer accounts gain that our team has been in.

Surya Patra: Whether because of the less competitive scenario, whether the pricing trend or the kind of a quantum is a commercial opportunity for us, whether that has gone better,

or gone up compared to the earlier situation or any sense on that, if you can, please provide.

Vinita Gupta: Yeah, pricing has been down little bit actually in the last couple of months. It's still a material opportunity, but at a little bit of a lower price.

Surya Patra: Okay, and just to ask one question on the progress of Etanercept in Europe, so, obviously, that we have seen the progress in Germany, but what time that you should be taking to have a kind of decent on ground presence in multiple European nations or meaningful European nations rather?

Vinita Gupta: The plan is over a 12-month period launching into different countries. Mylan has launched in Germany, Croatia, Finland and planning in France and Belgium, and after that another country. There's a whole sequence of launches across all of the markets, that are planned over the next 12 months.

Surya Patra: And that could be a kind of proportionate market share gain considering the kind of established competitors there. So, any sense on - likely market share gain for this product there?

Vinita Gupta: Yes, is very early to comment on market share gains. We know from what we've heard from our partner, Mylan, they are very satisfied with the launch in Germany, it's been a good start for them. But you know, it is yet to reflect into market share that should happen in the next six months or so.

Surya Patra: Thank you.

Moderator: Thank you. Next question is from Prashant Kothari.

Prashant Kothari: Yeah. My question is on Albuterol. By when do you think will be ramping up completely?

Vinita Gupta: Q4.

Prashant Kothari: And the second question was on the working capital side, we have seen an increase especially on the on the inventory front, how should we be thinking about it going forward?

Ramesh Swaminathan: The working capital has increased and as you very correctly pointed out it is because of two components; one is the inventories and the other is the accounts receivable itself. Accounts receivable has increased because the bulk of the sales in America actually happened in the second half of September, Glumetza, Albuterol and the like, and given the credit period out there, that still comes in as accounts receivable. It will normalize, as the sales of these products normalize over the next few quarters. It will certainly come down. In terms of operating days, it's about 144-145. This is in line with the recent past. Q1 was a bit of an aberration, but if we go back to Q4 of last year and the like, it is around the same vicinity.

Vinita Gupta: Also, to add Ramesh, on the inventory front, as we gear up for more launches, our inventory levels have gone up, We also have been working towards building inventories so that we can shift more of our supplies to the US through oceans that has been a proactive move.

Ramesh Swaminathan: That's the strategy. Absolutely. That's very well thought out Vinita.

Prashant Kothari: Okay, Thank you.

Moderator: Thank you. We will take one last question from Ritesh Rathod

Ritesh Rathod: Yeah. Good evening, everyone. Your margin expansion on a medium-term basis of 22%, would a large portion of it come from the cost saving side or would it be dependent on product launches, which you alluded on the injectables, inhalers and biosimilars, and why am I asking this question is on the cost saving side is because in the last five years, your employee expenses have moved from 13% to 19-20%. Your other expenses, excluding R&D is moved up by 300 basis points. So, would it be dependent on this product launches or there's enough cost lever on the operation side to do this?

Ramesh Swaminathan: We are focusing on several things. A year and a half ago, we actually started off with the consultants working on, the gross margins itself. Several initiatives taken there, alternate vendor strategies and the likes to bring down the overall procurement costs. That apart, there was a famine in terms of products that we released over the last three years, and that obviously meant that whilst our overall expenses went up, the sales growth was not as much. So, it's kind of correcting that situation We are working on our manpower costs, and a host of other things as well to bring within the range, which is acceptable. So, while the focus is to bring in a lot of quality products and the like, it is also equally on cost. The other part is the R&D line, we are taking steps to actually bring it down. The focus today is on more complex products. But if you look at the total quantum in terms of absolute numbers, it is hovering around Rs.1500 crores. And as a percentage of sales, it is around the 9%. Over the next several quarters, it will - tend to be a little lower, perhaps settling around the 8% range. With all of this, the EBITDA margins would creep up.

Vinita Gupta: I will just add, Ramesh, on the manpower cost points that you made. We are very confident of sustaining the current level that we've been able to bring our spend down to 18% from the 20% last year, and continuing to get operating leverage as our business grows in the next couple of quarters and certainly into the next fiscal year.

Ritesh Rathod: Wish you good luck for that. Thanks.

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

Dr Kamal Sharma: Yeah, I thank you for your participation in this call. And I do hope that you had satisfactory replies to your questions. In case you still have some doubt or something which is not answered please take it offline with Arvind or with Ramesh and we will do our best to make sure that you get your requisite answers and look forward to see you in the next quarter earnings call. Thank you very much once again and stay safe and stay good. Thank you very much.

Moderator: Thank you, sir. On behalf of Lupin Limited, that concludes this conference. Thank you for joining us and you may now exit the webinar.