



“Lupin Limited Q3 FY2021 Earnings Conference Call”

January 29, 2021

MANAGEMENT:

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Moderator: Hello everyone, welcome to Lupin Q3 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: Good morning, everyone. This is Kamal Sharma and I welcome you to the earnings call for Q3. 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 very strong quarter, where you see growth of 3.6% QoQ/5.4% YoY in the revenue line. There has been substantial improvement in the EBITDA margin, as we've been speaking about in our earlier earnings calls. The team has worked hard and delivered good EBITDA margin. I'm also pleased to say that our effective tax rate has substantially improved as most of our major subsidiaries have done well this quarter. We look forward to delivering similar performances going forward. To give you complete financial commentary and details, I now hand this call over to Ramesh.

Ramesh Swaminathan: Thank you, Dr. Sharma. Dear friends, welcome to Q3 FY21 earnings call. Happy to share with you a good set of numbers after quite some time. Let me walk you through the key aspects of our Q3 performance. Q3 has been a good quarter for us with sequential sales growth across all markets - highlighted by 3% QoQ growth in the India formulations business and 4% QoQ growth in the U.S. business with continuous ramp up of Albuterol. Despite the impact of weak flu season seen across various parts of the globe, we've been able to post sales growth both sequentially vis-a-vis Q2 FY21 as well as YoY vis-a-vis Q3 FY20. The operating EBITDA has also improved sequentially for the fourth quarter in a row, due to improvement in business mix and reflection of some of the cost optimization efforts on the profitability front.

Talking about sales - U.S. sales grew by 4% sequentially at US\$188 million in Q3 FY21, as compared to US\$180 million in Q2 FY21, and grew by 1% as compared to Q3 FY20. The sequential growth was driven by ramp up in Albuterol as well as new products like Lapatinib, Tacrolimus etc. The demand for seasonal products continues to be pretty weak on back of the weakest flu season in the last decade, leading to a fall in quite a few of those products as compared to the previous year. Other in-line products however, remain stable.

India region saw a growth of 5.4% YoY, since demand for acute as well as chronic products picked up as the market began to open up, leading to higher patient visits to the clinics. Despite the low contributions from COVID therapy



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products, we have been able to match IPM growth this quarter led by superior performance of our chronic portfolio. API sales de-grew QoQ with low volumes for some of our antibiotic APIs on account of a weaker flu season in most parts of the world.

Gross margins were up by 1.4% vis-a-vis the previous quarter at 64.9%, driven by improvement in the business mix across regions and continued moderation of freight rates. We did some excellent work on the manpower cost front. Employee benefits expenses in Q3 came in at INR7,070 million as compared to INR6,850 million in Q2 on account of increments rolled out during the quarter and certain one-time restructuring costs. However, we recognize, this is quite lower as compared to the previous years. Employee benefits have come down to less than 18%, as a percentage of sales from 20% seen in FY20. We will continue efforts to improve from the current levels.

On the manufacturing & other expenses front, there's a reduction, driven by lower forex losses and R&D offset by higher SG&A spend and higher royalty on partnered products.

Most important line from our perspective is the EBITDA. Operating EBITDA is 18.6% excluding forex and other income. However, the top line EBITDA is 20.4%, as you would recognize.

On the other operating income line, we saw the full impact of loss of MEIS export benefits for this quarter and barring the one-off income linked to litigation settlement recognized in Q3, this would have been about INR250 to 300 million on a normalized basis. To repeat again, Q3 operating EBITDA adjusted for the one-off is about 18.6%, excluding forex and other income, and this compares well with 16.8% in Q2, an increase of 1.8% as you would recognize.

The ETR came down to 15.9% with all our key subsidiaries reporting profits in Q3 along with the various initiatives taken to rationalize ETR. For the full year, expect the ETR to be in the mid-30s.

With this, I open the floor for discussions.

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 everyone an opportunity. I will first request Mr. Kunal Dhamesha to ask your question.

Kunal Dhamesha:

Yes. Thank you for taking my question. Good morning, everyone. The first question is on the specialty rationalization that we have done. Have all the



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benefits of that reduction in sales force and some of the front-end infrastructure cost efficiencies have flowed into this quarter or do we expect some more savings to continue?

Vinita Gupta: Kunal, they have flown into this quarter. We will take a stock of how things change over the next couple of quarters with regard to the COVID environment and related impact on the ability to reach the doctor's office, to determine if there is a need to do any further adjustments.

Kunal Dhamesha: Okay. Secondly, on the R&D expense which has decreased significantly in Q3, so what would be our expectation for Q4 and also for FY22?

Vinita Gupta: We expect to keep R&D at the 9% level. As you can see, we used to be at a 10% level as of the last fiscal year and currently managing it at the 9% level. We can expect to see that going forward.

Kunal Dhamesha: Okay. Thank you.

Moderator: Thank you, Mr. Kunal. Next question is from the line of Ms. Nithya Balasubramanian.

Nithya B: Quick question on the respiratory generic products and the pipeline. In terms of albuterol, what is the kind of market share ramp-up you are seeing? I think the weekly TRx data is showing a little bit of dip. So, any comments on what might be the reasons? And is there any capacity constraint?

Vinita Gupta: The market share is ramping up very nicely, Nithya. Typically, the monthly data is more accurate than the weekly, based on what we see. The latest monthly data that I have, shows 9% plus market share of the generic market. So, it's ramped up very nicely over the last couple of months. We continue to ramp it up, both from a supply as well as the customer share gain standpoint. We will continue to see that within this quarter and going into the next fiscal year.

Nithya B: Any comments on what kind of ramp up are you likely to see now that Perrigo has announced that they're unlikely to get back in the market this year?

Vinita Gupta: Yes, we're hoping to get to 20% plus share over the next couple of quarters, sooner rather than later.

Nithya B: Got it. Any updates on the Spiriva both the filing as well as the litigation?

Vinita Gupta: The litigation is ongoing. On the filing, we continue to make progress with questions that the agency has. So, still on track to launch it mid of next year i.e. CY22. Apart from Spiriva question, on the other inhalation pipeline, as we look at Q4 as well as FY22, of course we have the albuterol ramp-up, we have a couple of other products on the inhalation front - nebulas Performist as



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well as Brovana that we intend to bring into the market in the U.S. We have Fostair that we expect to get approval in the next couple of months and launch soon after. So, for the next fiscal year, it's these 3 products in the U.S. - Albuterol, Perforomist, Brovana and Fostair in Europe. In the following year, we would expect Spiriva as well as Dulera, hopefully.

Nithya B: Understood. Just a quick follow-up on Spiriva. So the kind of queries you're getting from FDA are the regular IR sort of queries or do you have like a minor CRL or what sort of queries are you trying to address? If you could throw some light on that?

Vinita Gupta: Yes, IR.

Nithya B: Okay. Thank you.

Moderator: Thank you. Next question is from Ms. Neha Manpuria.

Neha Manpuria: Vinita, just to reconfirm, you said Spiriva would be a mid-FY22 product or FY23?

Vinita Gupta: Mid CY22, so it's FY23.

Neha Manpuria: Okay. Fair enough. Second, in terms of our cost optimization, I think, Ramesh, you mentioned that some amount of it is reflected in this quarter. How much more of cost rationalization or optimization should we see, particularly given the specialty rationalization is behind us and R&D will probably now increase from here, as revenue ticks up?

Ramesh Swaminathan: Neha, as you recognize, this is a continuous effort. We have been working to improve upon our gross margins by looking at alternate vendor development, looking at routes to synthesis. We are also embarking on a digital journey and looking at the rationalization of our workforces. All of these are actually reflected in the numbers itself. As you'd recognize, it's a continuous journey, and we would continue to go down that path, and you'd see further improvements coming up.

Neha Manpuria: Would it be fair to assume that the incremental margin expansion from here would be dependent on probably our pipeline execution rather than cost rationalization?

Ramesh Swaminathan: I would say, it's going to be both. It certainly is going to be a function of the kind of products that we bring to the market, the kind of cost rationalization that will continue and the kind of productivity that we'd see on the R&D and the SG&A front in terms of operating leverage.



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- Neha Manpuria:** Okay. On the R&D front, if you could throw some light on our progress on the complex injectable and the biosimilar, where we are in terms of trials or filing. Any color there?
- Vinita Gupta:** Sure. On the complex injectables, we're making really good progress across the areas that we have focused on. On the depot products out of Netherlands, the first two products are ready to go into the clinic. Actually, the first product is going into the clinic this quarter. The second will go into the clinic in the next couple of months. We have the liposomal products out of ForDoz, where we're making really good progress as well. We would expect at least one filing in the next fiscal year. If possible, we'll try to get both the filings in the next fiscal year. On the peptides, we are making progress as well, getting ready to file a couple of products in the next few months and likewise on the iron colloid products as well. So, we have come a pretty long way on the complex injectables.
- On the biosimilars front apart from Etanercept, we made really good progress on Pegfilgrastim. Look forward to filing that in the U.S. this quarter and are getting ready to put together our go-to-market plans, build commercial capabilities and be ready to launch it in the next fiscal year or early the following fiscal year.
- Neha Manpuria:** And Vinita, besides peg, are we doing any other biosimilar for the U.S. market?
- Vinita Gupta:** Yes, Ranibizumab.
- Neha Manpuria:** Okay. And that goes into clinical trials this year?
- Vinita Gupta:** Yes, just started.
- Neha Manpuria:** Okay. And despite all of this, we will keep the R&D at 9% of sales?
- Vinita Gupta:** That's right.
- Neha Manpuria:** Okay. Thank you so much.
- Moderator:** Thank you. Next question is from Mr. Tushar Manudhane. Please go ahead.
- Tushar Manudhane:** Just on Albuterol, what kind of capacity utilization we are currently at?
- Vinita Gupta:** We are fully utilizing our capacity right now.
- Tushar Manudhane:** And so, this ramp up would happen over what period, so as to gain this 20% market share?



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- Vinita Gupta:** We are in the process. It's ramping up month after month. In this quarter we'll be able to produce more than the last, and we would see full ramp-up in the next quarter.
- Tushar Manudhane:** And roughly how many units per month, can you share the kind of number?
- Vinita Gupta:** Roughly, you can assume the market is 70 million units, and we are targeting 20% plus share. So, 14-15 million units. We'll have capacity to do more, but that's the kind of share that one should look at.
- Tushar Manudhane:** Got it. And then secondly on Spiriva, on the litigation side, we are in the district court currently. So any further development in terms of what is the time line for the outcome on the district court front at least?
- Vinita Gupta:** I don't have the timeline right now.
- Tushar Manudhane:** Okay. That's it from my side. Thank you.
- Moderator:** Thank you. Next question is from Mr. Prakash Agarwal. Please go ahead.
- Prakash Agarwal:** Sir, the first question is on the USFDA. Is there any dialogue that we are already into? We heard that the USFDA guys have started inspecting one of your competitors. So, is there an update on physical audit inspection dates? And is there any progress in the U.S. as well? Thank you.
- Nilesh Gupta:** Hi, Prakash. There's been document requests and the like that we've been answering, but there really isn't any traction on a firm date at this point of time. We're very hopeful with the fact that the first inspection for an Indian facility started a couple of days ago. So, we're hopeful that at least for the more meaningful mission-critical inspections, USFDA would increase their activity in India. We're hoping that it picks up. But by the time vaccination picks up, by the time travel opens up, it will definitely be late in the second half of the year when we would really expect for meaningful USFDA activity.
- Prakash Agarwal:** Okay. And from our side are we fully ready?
- Nilesh Gupta:** We are. We've actually gone back to the FDA on sites like Goa, Pithampur, Tarapur and we obviously expect the FDA to come there sooner rather than later.
- Prakash Agarwal:** Okay. Any take on the observations that you saw on the US plant? I mean while you maintain that you're ready across facilities, you again saw those 13 observations. So, what's your take there? And by when do you plan to resolve that?
- Nilesh Gupta:** Maybe I can start up and Vinita can add. Obviously, we were not happy with the fact that there were 13 observations. This was a tough, very long



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inspection. But that being said, it is what it is, and we have to be able to deal with it. Clearly, there were areas for improvement in Somerset. I wouldn't generalize that for the rest of the operations, because we have a pretty bespoke kind of plan for each facility, as we gear up remediation activities. For example, you saw in the past that Mandideep had a significant number of observations, which eventually went to a warning letter. There we have a very deep transformation program. In Pithampur too, we've had a very deep transformation program. Not the same way in Goa or Tarapur even for that matter. So, I wouldn't generalize across the board. Obviously, there is a deeper transformation that is being conducted right now in Somerset as well. There were specific areas of improvement there. Some of the things that happened there do not happen elsewhere. But I think, suffice it to say that this is one of our biggest priorities to get it right. As you know, we had a very solid start in 2020 in the first calendar quarter we got the EIRs for 6 facilities, and still being cited for some of the observations that we have been cited for in the past. So, we're moving in the right direction. Job is not done. There's still work to be done on the compliance front.

Prakash Agarwal: Okay. Thanks. And the second question is on R&D. You mentioned about R&D being at around 9%. So, is this for FY22 and FY23 as well and what's the kind of filing and launch expectations on both these years?

Nilesh Gupta: R&D would remain at 9% for FY22 as well. We're kind of in the middle of our budgeting, so we're still seeing whether there will be a slight increase or not. We'll come back later with more color on the absolute number as well as the filings and launches. In general, we file about 30- 35 products. About 15 to 20 of them are oral solids, first-to-files, exclusive kind of opportunities, few ophthalmics, few derma. The injectable pipeline, as Vinita shared, is starting to pick up. We're hoping sooner rather than later, we start getting to the six-plus filings each year on the injectable side, with a couple of them being the extremely complex ones as well. We're getting to a very good pace on the inhalation. On the inhalation, we're increasingly looking at three to four products each year. Even right now, we've taken three or four exhibits, which will turn into filings for next year. The inhalation pipeline is picking up. All in all, together, getting to 30-35 products for the US and obviously, a subset of that goes to other geographies as well.

Prakash Agarwal: Okay, and this year is clearly an aberration, we are at six for nine months?

Nilesh Gupta: Yes. We typically do see this lumpiness in Q4. You will get more filings in Q4. Some of the exhibit dates moved out because of scheduling issues with CROs and the like when COVID was more an issue in India, but you'll see that starting to even out.

Prakash Agarwal: Okay. Thank you. I have one more, but I will join the queue. Thank you.

Moderator: Next question is from Mr. Surajit Pal. Please go ahead.



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Surajit Pal: Improvement in your gross margin is entirely because of favourable product mix this time?

Ramesh Swaminathan: Yes, there are several factors. There has been this continuous effort to kind of shore up the gross margins, which has been happening for some time now. The second, of course the sales mix, including Albuterol coming in. The third, in terms of lowering of the overall freight cost itself vis-a-vis the previous quarters.

Surajit Pal: Okay. The last one is - what was your branded sales in US during this quarter?

Vinita Gupta: It was ~US\$2 million.

Surajit Pal: And what would be the number of headcounts currently in the branded business?

Vinita Gupta: We have a 40 people salesforce.

Surajit Pal: Okay. Thanks and all the best.

Moderator: Thank you. Next question is from Mr. Sameer Baisiwala. Please go ahead.

Sameer Baisiwala: Thank you very much and good morning, everyone. Nilesh, how we are thinking about the plant inspection for Spiriva?

Nilesh Gupta: We've been inspected in the past for Spiriva already. Like Vinita said, there is an active conversation going on with the USFDA. There are still some hoops to be covered. We still feel very good about that CY22 launch.

Sameer Baisiwala: And a plant visit or plant inspection won't be a bottleneck, is it correct?

Nilesh Gupta: Like I said, we've been inspected in the past, specifically for Spiriva. But I think there's still a little bit of ground to be covered

Sameer Baisiwala: Okay. And Nilesh, clearly, you guys are very confident of mid-2022 launch. But the time is not enough for the court case to get resolved until then. So how are you thinking of resolving that?

Vinita Gupta: We would have district court decision within a year. I don't have the exact date, but we would expect it within a year.

Sameer Baisiwala: Okay. That's great. And the second thing is on biosimilars. How is Enbrel doing in the market? Any color on the market share etc.? And second is on Pegfilgrastim. Being a third or fourth entrant, do you think there would be enough value left in the market, given that even the current incumbents are struggling a fair bit?



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Vinita Gupta: On Etanercept, Sameer, the ramp-up is slow. I mean it's more of a branded build in the European market. Our partner, Mylan, has chosen markets where we have the opportunity to maximize from a pricing standpoint. So far launched in Germany, Belgium and one smaller market, but we're getting ready to launch in France. We would expect in the next 12 to 24 months for the product to be rolled out in all the key markets. So, it's a slow buildup of share.

On Pegfilgrastim, we certainly believe that it continues to be an attractive opportunity based on the go-to-market plans that our team has built and the segments that we are targeting. We believe that it should continue to be a reasonable opportunity, especially given the dynamics in the biosimilars market, where you don't see the kind of price erosion. Of course, we'll have to earn our share, which our team is working on the strategies to make sure that we do. But I'm looking forward to that launch in CY22.

Sameer Baisiwala: Okay. And with your permission, final one. Vinita, what are your updated thoughts on Solosec and its ramp-up going forward? Do you think it would remain slow or anything to really accelerate it?

Vinita Gupta: There are a couple of accelerators, Sameer, but the biggest decelerator is COVID. With the COVID environment, just the access into the OB/GYN office for acute care product, in particular, has proven to be really tough. The accelerators are -- we continue to get additional formulary access through recent efforts. We have been able to get the product in. So, that is a positive. We have the trichomoniasis indication, which is an opportunity to reposition the product. A really nice opportunity in the summer. We expect that in June. Right now, we're gearing up to launch the trichomoniasis indication successfully in June. I'm hoping that with the vaccine rollout, things start improving by mid of this year. I'm hoping that we start seeing real traction in the second half of this calendar year. I mean so far, when I look at it quarter-on-quarter, the scripts have kind of flattened. With some of the gross to net improvements, one has seen some pricing improvement quarter after quarter. But a meaningful build, would be after the trichomoniasis indication launch and for the COVID environment to abate a bit as well.

Sameer Baisiwala: Okay. Thank you.

Moderator: Thank you. Next question is from Mr. Dev Daga. Please go ahead.

Dev Daga: Sir, I wanted to know given that we have had an Albuterol ramp up this quarter, so why has our top line not grown proportionately as compared to the previous quarters?

Ramesh Swaminathan: We said that Already. Vinita might like to address this question, but that's essentially because of the fact that there has been a very poor flu season



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across various parts. So, products in America didn't sell as much. Equally for API products, the demand for the antibiotics across the globe was very poor.

Vinita Gupta: If you look at our growth, we still had year-on-year growth in the US of 5% despite the fact that it's one of the weakest flu seasons in a while. All of the demand of the flu products, the cephalosporins, gTamiflu has been really, really weak. Obviously, we've not had contribution from flu products. The other area compared to year-on-year is Metformin, that we unfortunately had to withdraw because of the NDMA issue, we relaunched in September and are in the build mode right now. So, when you compare to the last year, both the flu products as well as Metformin products are really missing in our top line. The flu products, we'll see if we have a late flu this quarter, but the Metformin products are building right now. gGlumetza was relaunched, and we are well on our way to earn our share back again. We expect to also launch the gFortamet product in this quarter.

Dev Daga: Okay. That helps. And my second question, we have seen a very good growth in the rest of the world business this year. In the next quarter, can you see a similar growth in the business, or will we see the other geographies showing better growth?

Ramesh Swaminathan: The markets are growing. If you look at, for example, Brazil, we have been growing steadily over the last few quarters. We've done a great job there. Other markets are just about opening up. For example, if you look at markets like the Philippines, it's perhaps going through its worst depression in several years. Mexico is just about opening up and it did okay in Q3. India, in terms of acute therapy, the overall prescriptions have been lower. We expect, the rest of the world, including India, to certainly ramp up in the quarters to come.

Dev Daga: Okay. And what about the other geographies? Where can we see growth concentrated, Europe, US?

Ramesh Swaminathan: Dev, if you look at America, we have got Albuterol in the full quarter ahead of us. So, there would be a ramp-up there. We've got products for Europe also, NaMuscla is still ramping up. All of this will certainly see growth, as would South Africa. For South Africa, Q4 is generally a very good quarter.

Nilesh Gupta: And in India also, Ramesh. Obviously, we'll get back to that double-digit growth in the next year, which is single digit at this point of time.

Dev Daga: Okay. Thank you.

Moderator: Thank you. Requesting everyone to introduce yourself before asking question. Next question is from Mr. Nitin Agarwal. Please go ahead.

Nitin Agarwal: Hi. Thanks for taking my question. Vinita, just one question on the QoQ business that you talked about in the US sales. Barring ProAir, how has the



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portfolio been on QoQ basis? How has the other ex-gProAir portfolio grown in the quarter?

Vinita Gupta: Ex-Albuterol, the baseline business has been fairly stable, and we've had some contribution from the new products that we've launched in the last couple of quarters. For example, lapatinib has grown a bit. We're in the process of ramping up products like gVimovo and we also launched tacrolimus. We should see a better contribution from tacrolimus this quarter and also gApriso. So, there are a couple of products apart from albuterol, but the largest contributor being albuterol in terms of QoQ growth.

Nitin Agarwal: The reason I was asking, Vinita, QoQ, we had an US\$8 million increase in revenue. So, it seems given the fact gProAir (albuterol) should have contributed a fair bit. So that seem a little surprising in terms of being a little on the lower side.

Vinita Gupta: Yeah. gProAir has been a good contributor but the others are smaller.

Nilesh Gupta: And we already mentioned about the flu season products. Those numbers are depressed in Q3 even over Q2 a little bit.

Nitin Agarwal: Okay. Perfect. And secondly - you were mentioning about the key launches over the next couple of years. Where does gSuprep fit in this sort of schematic?

Vinita Gupta: It's FY23 launch.

Nitin Agarwal: And is it going to be a reasonable launch for us? How are we looking at it?

Vinita Gupta: Yes. I think it's a reasonable-sized product. It's US\$200+ million product, where we are the first to file, and we have a final approval.

Nitin Agarwal: Okay. Perfect. And another one, Ramesh, on the ETR, how should we look at ETR now over the next couple of years? Do we see it coming down to 30% towards the next couple of years?

Ramesh Swaminathan: Yes. This year, we'll perhaps see an average rate in the mid-30s. But going forward, you certainly could expect lowering of the ETR.

Nitin Agarwal: Okay. And sorry, if I can squeeze in last one. Vinita, on the specialty side, you mentioned that the field force now is 40-odd people. And given the size and the structure that we have for the specialty business now, what typical size of specialty business do we need to start breaking even on this business?

Vinita Gupta: Depending on the margin of the product, at around US\$20 million.



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- Nitin Agarwal:** US\$20 million annualized. That should be enough for us to break even on this business model. Thank you.
- Ramesh Swaminathan:** The other way to look at it is that we also get other products into the portfolio, so that we can actually defray that expense base over the higher, larger revenue base.
- Nitin Agarwal:** Right. Thank you.
- Moderator:** Thank you. Next question is from Mr. Prakash Agarwal. Please go ahead.
- Prakash Agarwal:** Yes. Thanks for the follow up. So just on this 40 people MR, is there further rationalization or cost savings possible there or this is the minimum threshold we want to keep as we also talk about adding more products?
- Vinita Gupta:** We are in the process of looking at what we need for the trichomoniasis launch, Prakash, which we want to do effectively and looking at other products as well. We'll take a call in the next 2 quarters depending on both, in terms of what is the optimal size.
- Prakash Agarwal:** Okay. Got you. And I don't know whether I missed this. This other operating income, you said there's some litigation income. Could you explain that, please? I mean because you mentioned that this INR300 million to INR400 million kind of the export incentive that was there. But what's the remaining INR700 million?
- Ramesh Swaminathan:** We made that very clear. The annualized number would be about INR250 million to INR300 million. This is because of the fact that MEIS export benefits have been called off by the government. This quarter, we recognized some litigation settlement, and that's reported in the overall figure.
- Prakash Agarwal:** Yes. I understood that. But if you could give some details on litigation settlement? What is this related to?
- Ramesh Swaminathan:** Unfortunately, we're not in a position to share further details at this stage.
- Prakash Agarwal:** So, you just calling out this is one off at this point?
- Ramesh Swaminathan:** That's absolutely correct. We're making it very clear that this is one-off.
- Prakash Agarwal:** Okay. Perfect. And second one also for you, Ramesh. On the tax rate, so there's a clear call-out on some of the subsidiaries, which have turned profitable, and you mentioned that you expect they'll likely to be so in future. So how do we see annualized tax rate for this year, next year and year after, ballpark?



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Ramesh Swaminathan: This year, it would be in the mid-30s, but progressively it will certainly come down, because the most important subsidiary for us is America. Firstly, given the kind of products to be introduced; second, the kind of rationalization that has taken place, it would be profitable. Other was essentially Brazil. Brazil has also turned a corner. It's profitable at this stage. So, things would only progressively become better for us from an ETR perspective.

Prakash Agarwal: So around 30% for next year?

Ramesh Swaminathan: Yeah, slightly lower.

Prakash Agarwal: Okay. Understood. Perfect. That's all. Thank you so much.

Moderator: Thank you. Next question is from Mr. Rajakumar Vaidyanathan. Please go ahead. Please introduce yourself before asking question. Thank you.

Rajakumar V: Yeah. Good morning. My name is Rajakumar. I'm an individual investor. Thank you for giving me the opportunity to ask questions. I have a couple of questions. The first one is - with the Democrats coming back to power in the US, just wanted to know what is the pricing scenario the management is expecting? Do you expect any pressure on the pricing, given that you have kind of said that they will make the healthcare more affordable going forward? And second question is on the albuterol. Just wanted to know how is the competitive landscape given that Cipla also has a significant share. So just wanted more color on this. I'm sorry if this was answered earlier, I just joined the call a little late. Thank you.

Vinita Gupta: On the pricing environment, it's early days, but we really thought that both Democrats as well as Republicans, it was bipartisan support in terms of looking for ways and means to make drugs more affordable. Especially pricing of high-priced brands, biologics, oncology drugs would likely be under pressure. But we really see it as an opportunity for affordable medicines, the part of the business that we participate in from a generic side. Obviously, all of our generics are affordable medicines as well as biosimilars i.e. affordable versions of biologics. We see it as a positive for the generic side of the industry.

On albuterol, certainly Cipla had a head start from a timing perspective into the market. After we launched, we ramped up our share in couple of months to 9% plus, while still ramping up our supply. We see a really good opportunity for us, given that we are the only true generic to ProAir, which is the largest part of the market. With Perrigo going out of the market, Lupin is the only true generic to ProAir and has the ability to ramp up to be the largest product from a generic perspective. We're looking forward to the next couple of quarters, this quarter, next quarter to be able to ramp the product up.

Rajakumar V: Thank you, Vinita. That's helpful. Thank you.



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Moderator: Thank you. Next question is from Mr. Rakesh Jhunjunwala. Please go ahead.

Rakesh Jhunjunwala: Good morning, and congrats on the fine performance. Ramesh, why should our rate of tax be in the 30s? Your Indian income is 25%. The rate of tax in America is 20%. You have carryforward losses in Americas. I don't understand why our rate of tax -- it should probably be, if anything, beyond 25%?

Ramesh Swaminathan: Mr. Jhunjunwala, the fact is we still have our subsidiary in Amsterdam, in Holland, which actually is a research subsidiary, which is to still to make profits out there, which will not commercialize the products. So that is the reason why it is what it is.

Rakesh Jhunjunwala: That's a small subsidiary. How much loss can you incur about INR1,000 million, INR500 million?

Ramesh Swaminathan: Yes, America has turned profitable this quarter. Going forward, as I said, it will certainly impact -- there will be a reduction in overall ETR.

Rakesh Jhunjunwala: Anyway, congrats on a fine performance. Thank you.

Moderator: Thank you, sir. Next question is from Mr. Shyam Shrinivasan.

Shyam Shrinivasan: Hi. Good morning. Good evening. Thanks for taking my question. The first one is on the US generic pricing environment, Vinita. Anything you can share? 2020 was kind of benign. But calendar year 2021, do you think things could get worse off from a pricing perspective?

Vinita Gupta: What we've heard at JPMorgan from all of our peers as well as our customers was a relatively stable environment on the generic front from a pricing standpoint. We are hoping that it continues to be the low single-digit erosion.

Shyam Shrinivasan: Yes. Just extending that. So, the conversations with the distributors, the supply chain in the US, is there the same angle that we had last year, which is the reliability of supply. Do you think that theme continues to remain in 2021?

Vinita Gupta: Yeah, reliability of supply is very important to them and that continues.

Shyam Shrinivasan: Got it. Thank you. Second one is on Levothyroxine. Can you help us understand? I think we've talked about contracted market shares in the past. So where are we right now? And what's the kind of upside on Levothyroxine?

Vinita Gupta: We are at 17% plus of the generic market share, roughly 14% of the overall market and still working towards that 20% plus share.



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- Shyam Shrinivasan:** Yes. So, Vinita, is that like a hurdle you think or -- we have done well, so I'm just trying to see can we go higher? It's a large market, but is there any impediments to taking share higher than that?
- Vinita Gupta:** We think that unless we have an opportunity, just given the new entrants that have come in as well, it makes sense to really target that kind of share and then see, depending on the opportunity going forward. But it's a material product and switching share is not that easy as you've seen over the last couple of years. Customers are fairly reluctant to switch share, just given that it's a narrow therapeutic index product.
- Shyam Shrinivasan:** Got it. Last couple of questions. We have talked about the product momentum going from whatever single-digit in the US to healthy 25, 30 products. Can you help us understand from which plants these product approvals could likely come?
- Vinita Gupta:** A number of our plants. For example, all of the inhalation products, if you look at Albuterol is from Pithampur Unit-3; Spiriva is from Pithampur Unit-3. Our nebulizer products are outsourced, they're contract manufactured. Fostair is Pithampur Unit-3 as well as Coral Springs. We have both sites qualified for Fostair. In fact, we are qualifying both sites, US as well as India for a couple of other products also, where there's government channel business that we can access potentially. We have the near-term product from these sites. And then we have products coming out of Nagpur, we have products coming out of Aurangabad, we have products coming out of Pithampur Unit-1.
- Shyam Shrinivasan:** Got it. So largely, the unaffected plants. We have not been building in anything coming out of some of the OAI affected plants. Would that be right? Would that understanding be correct?
- Vinita Gupta:** That's right. I mean our material opportunities are from these sites that I just mentioned.
- Shyam Shrinivasan:** Got it. And my last question is on the PLI scheme, the one that we had the first results come out in the antibiotic space. I was surprised to not see Lupin, so -- but maybe we were never in consideration. So just wanted your thoughts on the scheme in general? And do you think it makes sense or did we pass it completely? Thanks.
- Nilesh Gupta:** The second version of the PLI scheme is going to be even more powerful than the first one. They still have to announce the entire list. There are some smaller products that we are playing a role in the initial round. I think there still has to be overall alignment with the business strategy. But I think the second version of the PLI scheme gives room for a lot more to be done, and that is somewhere where we believe we will participate meaningfully.



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- Shyam Shrinivasan:** Nilesh, in the second version, is it the rest 46, 47 drugs or you're talking about the formulation PLI?
- Nilesh Gupta:** The formulation one.
- Shyam Shrinivasan:** Got it. And do we know any timelines because it seems to be in the press, but do we know anything?
- Nilesh Gupta:** No, I think it's still in Parliament. I think it's still be a couple of months away. I do see this as something, which rolls out in the next two quarters, though.
- Shyam Shrinivasan:** Got it. Thank you so much. All the best.
- Moderator:** Next questions is from the line of Mr. Sameer Baisiwala. Please go ahead.
- Sameer Baisiwala:** Hi. Thanks for the follow up. Vinita, can you talk a bit more about commercialization angle for Fostair once you get the approval in the next couple of months? What sort of a market share ramp-up do you expect over a year or two and the competitive scenario for this?
- Vinita Gupta:** Yes, it will build because it's a branded like product. So, it's going to be building over the next two years. We will start in U.K. but have plans for all the other countries as well, Germany, Italy, France, Spain, the main countries, which form the majority of the Fostair brand market. From a competitive standpoint, we believe that we have the first mover advantage but think that there may be one or two players behind us. And for a EUR600 million product, it seems like with two or three players, it is still going to be a reasonable market.
- Sameer Baisiwala:** Any indicative pricing that you think once the competition settles down? It's just a broad range, does it go down 50, 60, 70, 80? Anything that you can share?
- Vinita Gupta:** Sameer, I don't have it on the top of my head, but I know that it operates more like a branded market, just given that you need to have a sales force in key markets like the U.K. I would think that the pricing strategy would follow the investment model as well.
- Sameer Baisiwala:** Okay. Thank you very much. And one more how is company thinking about M&A opportunities going forward?
- Vinita Gupta:** We're focused on specialty build where we can. And apart from specialty, also looking at areas that we can accelerate on the generic front, like injectables in particular, for the U.S. Opportunistically also for India to scale up our business, especially in therapy areas where our share is not at the top level.
- Sameer Baisiwala:** Okay. Thank you so much.



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- Nilesh Gupta:** Maybe we take one last question.
- Moderator:** Thank you. Will take one last question from Mr. Ritesh Rathod and then we'll go for the closing comments. Ritesh, please go ahead.
- Ritesh Rathod:** Yes - you mentioned a 20% market share for albuterol, which is 40 -- 50 million devices. So, when you said 9% market share, you mean you are at 6 million, 7 million devices annually?
- Vinita Gupta:** Yes. Roughly.
- Ritesh Rathod:** Yes. Okay. And second, on the cost optimization front, for each line item, whether it's employee cost, R&D and other costs. You mentioned about R&D about 9%. But for the other 2-line items, on more on a medium-term basis, where we are in the journey? Like what we are targeting as optimization from the percentage to sales?
- Ramesh Swaminathan:** Yes. From our perspective, we are saying that our EBITDA margins should be actually about 20% to 22%. If there are products being introduced, it could spike to a higher level. But I think the base level should be about 22%. Our endeavor is to make sure that the cost lines are contained in such a manner, the EBITDA margins reach those levels.
- Ritesh Rathod:** So, would it come more from other expenses or R&D will go down as you scale up or employee cost?
- Ramesh Swaminathan:** It comes from all lines. From our perspective, it is of course on the gross margins, making sure that the ramp-up on the manpower doesn't happen as much, and of course, the operating leverage clicks in and R&D productivity, for sure. All of these will contribute to keeping the EBITDA margin.
- Ritesh Rathod:** And Ramesh, on the EBITDA, is there any forex gain or loss element within the EBITDA number?
- Ramesh Swaminathan:** We reported 18.6% without taking into account the forex. The forex loss for this quarter was INR280 million.
- Ritesh Rathod:** Okay. And just on the first question of 6 million, 7 million devices, I presume it's not fully reflective of the quarter. It would be month end over the quarter.
- Vinita Gupta:** Just think about it as annualized 20% target.
- Ritesh Rathod:** Okay. That's all from my side.
- Moderator:** Thank you. I now hand the conference over to the management for closing comments.



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Dr Kamal Sharma: Thank you very much for your contributions and look forward to connecting with you in the next quarter. If there are some questions, which have not been answered, you can always deal with them off-line with Mr. Arvind Bothra and Mr. Ramesh Swaminathan. Thank you very much once again for your participation. Bye for now.

Nilesh Gupta: Thank you everybody for joining so early. Bye-bye.

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