



February 14, 2020

**BSE Limited**

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P. J. Towers,  
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**MUMBAI - 400 001.**

✓ **National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**Mumbai - 400 051.**

**Dear Sir/Madam,**

**Sub: Q3 FY20 Earnings Conference Call.**

Pursuant to Regulation 30(2) read with Schedule III Part A(15) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Q3 FY20 Earnings Conference Call on Thursday, February 6, 2020 at Mumbai.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,  
**For LUPIN LIMITED**

**R. V. SATAM  
COMPANY SECRETARY  
(ACS - 11973)**



**Encl.: a/a**



## “Lupin Limited Q3 FY20 Earnings Conference Call”

**February 06, 2020**



**MANAGEMENT: DR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**  
**MS. VINITA GUPTA – CEO, LUPIN LIMITED**  
**MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**  
**MR. RAJIV PILLAI – SR VICE PRESIDENT, CORPORATE PLANNING, LUPIN LIMITED**  
**MR. ARVIND BOTHRA – HEAD, INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**



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**Moderator:** Ladies and gentlemen, good day, and welcome to the Lupin Limited Q3 FY'20 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing “\*” then “0” on your touchtone telephone. Please note that this conference is being recorded. I would now like to hand the conference over to Lupin management. Thank you and over to you all.

**Dr. Kamal Sharma:** Hello all and Welcome to the earnings call of Lupin quarter 3 results. I believe you have read through the results already. You would have seen that on the revenue line, there is a decline of 2.7% sequentially and 2.8% y-o-y. Q2 of this financial year and Q3 of last financial year, both had other income in them. So, if you adjust for that, then you would see 1% growth sequentially and 2.9% growth y-o-y. Accordingly, the gross margin is flat sequentially and is up by 0.7% y-o-y. You also see the EBITDA margin for this quarter is 14.1% as against 18.9% for corresponding quarter. The 9-month average EBITDA is 18.5%. We hope to end the year with around 18% EBITDA, and that is where we start off from, for the next financial year.

There are 2 other events that I need to share. First is the sale of Kyowa Pharmaceuticals, our asset in Japan, which was done looking at the business environment. The other one deals with impairment of intangible assets. This again goes to lighten our balance sheet and improve our ROCE, and therefore, it's a positive decision for us. For any questions or any details that you may like to know, I'll first hand it over this call to Rajiv, and thereafter, we will open the floor for questions.

**Rajiv Pillai:** Thank you, Dr. Sharma. Good afternoon, friends. Welcome to the Q3' FY'20 earnings call. Like Dr. Sharma spoke of, I would first want to address the 2 exceptional items that you see presented in the results and in the PR. I would explain each of these and then go to the normalized operational results for better clarity.

Firstly, we had the Kyowa divestiture that was announced in November and finally, completion of the transaction took place on December 17. We see in the books, a one-time pretax accounting gain of Rs, 1,291 crores. Against this there were taxes, and the net amount of gain that you see is Rs. 997 crores for the quarter, which is a one-off item.

The second exceptional item that you see in the numbers is the impairment of the Gavis intangibles. Certain IPs of the Gavis portfolio were reevaluated looking at the U.S. market conditions, and we have decided to take a provision for impairment. The amount is Rs.1,579 crore, roughly about US\$ 228 million on the pretax line. Linked to this, there were certain deferred tax assets, which we also decided to reverse in relation to the Gavis transaction. So total impairment was US\$ 288 million. The tax line contains a charge of about Rs. 405 crore and the total impairment, therefore, we have taken is about Rs.1,958 crores on account of the Gavis transaction. I'm sure you would have questions on the tax line, which clearly shows that there's almost Rs. 700 crores one-off that's lying in the reported numbers.



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Dr. Sharma has talked about the benefits of it. I would just like to say that with the Kyowa proceeds, we would be acting on deleveraging our balance sheet. The Gavis impairment improves our PBT. It positively impacts our tax rate, ETR. Also, the lightening of balance sheet on account of both these events improves the ROCE by close to 300 basis points.

Moving on to the operational highlights. The results that you see for Q3 have been restated for Kyowa. All the results that you see are as per the Ind AS standards on a comparable basis, except where in the PR, we may have specified that's not the case. Sales for the quarter came in at Rs. 3,716 crores. This was 1.1% up versus the previous quarter and on a YTD basis, you see a y-o-y growth of 8%.

Gross margins came in at 63.4%. Like we discussed before, it's flat and also shown an improvement vis-à-vis the previous year by about 0.7%. EBITDA margin came in at 14.1% versus the previous quarter EBITDA margin of around 17.1%. This was impacted by lumpiness in expenses on account of sales promotion, a slight uptick in R&D investments as well as some of the remediation activities that are ongoing.

The YTD EBITDA number has come in at 18.5%. We expect the Q4 number to be higher than the Q3 number. So eventually, for the FY '20, we should be at the lower range of the 18%-20%, expectation that we set during the course of this year.

Those were the key highlights, and I would now like to open the floor for questions.

**Moderator:** Thank you very much. Ladies and gentlemen, we will now begin the question-and-answer session. First question is from the line of Surya Patra from PhillipCapital. Please go ahead.

**Surya Patra:** Just a couple of clarifications. Is there any one-off item that is there in the other expenses line item?

**Rajiv Pillai:** Do you mean to say manufacturing, other expenses together?

**Surya Patra:** Yes.

**Rajiv Pillai:** There was some restatement. So that has happened across the quarters. But nevertheless, like I spoke of, there has been an increase on three counts, specifically increased sales promotion activity, increased investments in R&D and some of the remediation work that's ongoing. Just to clarify, we do not expect this to be the level. This would certainly go down as we go ahead.

**Surya Patra:** Yes. Is it possible to quantify, the one-off portion in this? This is giving a kind of a suppressed margin scenario for the quarter, and so it would be better if you can just quantify the one-off portion, if not separately mention about each item.

**Rajiv Pillai:** Like I said, it will not be Rs. 1,240 crores, it should be below Rs. 1,200 crores.



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- Surya Patra:** Yes, of course, that includes the R&D spend obviously, what you have mentioned
- Rajiv Pillai:** R&D for the quarter came in at about Rs. 422 crores and we guided for about Rs.1,600 crores for the whole year, and we are confident of staying within that number.
- Nilesh Gupta:** Rajiv is not giving specific details of the 3 items because it's really spread across those 3. But this Rs.1,240 crores should be more in the level on Rs.1,200 crores on a regular basis. And if you see in the previous year as well, it was Rs.1,220 crores. In fact, Q2 was a little depressed because of restatement of certain expenses. But otherwise, this is more like Rs.1,200 crores.
- Surya Patra:** Okay. So then the margin scenario, if we factor that, okay, as per the presentation also, you have mentioned it is EBITDA of 14%, which obviously includes the other income. If we remove that other income portion, then the margin scenario looks really suppressed 11.4% or something like that. So that is relatively low. Even if there would be some improvement, what you are mentioning because there would be a correction in the other expenditure line. So it will not be kind of a level, means it would still be a kind of a much lower level, what we have been seeing, that is one. And secondly, on the R&D expenditure side, so currently after the disposal of this Japanese business, the percentage of sales-wise, if you consider the ROCE spend seems really elevated. So that means the margin outlook is likely to remain very suppressed going ahead in the near future. Is that the kind of outlook that we are talking about, sir?
- Rajiv Pillai:** Surya, what I was saying earlier was that we should look at this not just on a quarterly basis, but this evens out, there is always lumpiness. So, for the full year, we are confident of being closer to the 18%, maybe a bit shy of the 18%, but we still will be closer to the 18%. And yes, that's the way it would look.
- Nilesh Gupta:** I think pointedly on the other income, there is nothing exceptional at this point of time. We don't see that number changing significantly over the quarter and there's no sense in stripping that number out and then trying to work out the EBITDA. The reported EBITDA was at 14.1%. Like we said, even Q4 onwards, we would expect improvement on that. I don't think Q4 gets back to that 17%-18%, but Q4 definitely gets better than that 14.1%. Our outlook certainly is positive from this. I think Q4 onwards, we really see growth from this. We see it getting back to basically averaging the year close to that 18%. Obviously, next year on, we expect further improvement on that EBITDA margin.
- Surya Patra:** Okay. And on the R&D side, anything that you are guiding, sir, for next year, why, because this year number considering the Japan revenue, it is still okay about stripping it out then looking at the number of the current year size that would look really elevated.
- Nilesh Gupta:** , Yes, obviously, given that we took it out end of December. Obviously as a percentage of sales, it looks higher. Our intention is to keep it in the 10% of sales. So that would be the endeavor. There's a little bit of sales drop right now, so, it looks elevated currently. But we guided earlier,



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that on an absolute term the R&D would remain the same level. It is more or less at the same level in this fiscal. Next year, also, we see a marginal increase at best, or otherwise, it's going to stay flat. That's despite the fact that sales would grow even minus the Kyowa.

**Surya Patra:** Okay. And on the debt repayment side, when do you really see that, okay, this number means that would really be implemented? You see that is happening this quarter? Or it would be happening subsequently?

**Nilesh Gupta:** We certainly see part repayment happening in this quarter itself. Like we had said earlier, in the near term, that's what we use these proceeds for. We're doing that and we have talked about the 0.08 net debt to equity. I think that will become debt to equity, instead of just the net position with the cash that we are holding. So certainly, this quarter, we'll make part payments to further reduce the debt position, and that will give us a little bit of reduction in the interest cost as well.

**Surya Patra:** Just last question on the business side, sir. So on the Levo, or can you tell something about the kind of a ramp up that you would have seen after the commissioning of the new plant? And how important the product has become so far? And what is the kind of endeavor to achieve next year on this product front?

**Vinita Gupta:** We are ramping the product up. We got the approval against all 3 RLDs in November and that's really enabled us to gain share on a like-to-like basis against the major players. December onwards, we have started building up share and have got reasonable share at this point in time, which you will see in this quarter's results. We are still in the ramp-up mode and I think we have taken half of what we have targeted so far and continuing to work towards building up share in the product. We expect Levothyroxine to make a reasonable impact this quarter onwards and will certainly be a major product for us in fiscal year '21.

**Moderator:** Thank you. Next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

**Neha Manpuria:** What should we look at the cost level for next year? Because I'm assuming some of this remediation expense could continue. Rs.1,240 crores versus Rs.1,200 crores does not look meaningfully different to move margins.

**Nilesh Gupta:** Absolutely. first of all, you are right. What we just meant is that there's a little bit of increase, which will even out. Even if you look at it on a year-on-year basis, it's basically Rs. 20 crores more. Obviously, the story going forward is not just about cost reduction. It is also margin expansion through ramp-up of important products like Levothyroxine, growth in markets like India, growing other products in the U.S. as well, building on our specialty and then there is a cost optimization effort as well. Both of those are what keep us in that 18-20%.

**Dr. Kamal Sharma:** And overall operating leverage...



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- Neha Manpuria:** So, will there be some cost of optimization benefit that we had talked about last year going forward? Or is this the pace we should assume?
- Nilesh Gupta:** Yes, right now, there's a very small number. The number in Q4 is expected to be, again, marginally better than what we have here. But next year onwards, we expect a significant improvement. Our cost optimization measures are in the direct and the indirect lines. So sometimes, it really should reflect in a gross margin increase, actually, when we do, for example, a replacement of an API or an intermediate or the like. And there are certainly some direct measures that we have taken, for example, earlier, we scaled down the size of the sales force in Japan. We scaled down the size of the R&D and sales force team in the U.S. We scaled down R&D in India as well. And that was obviously something that's already gotten into the numbers. Some of it has come, a good part of it is still to come.
- Neha Manpuria:** Understood. And Vinita, if you could give us an update on Solosec, what was the number for branded sales in this quarter? And how is that ramping up?
- Vinita Gupta:** It's actually ramping up nicely, still early days with the changes that the new leadership has made in the business. But we made a material change in our coupon strategy to be able to improve the pricing and revenues of the product. We're very pleased to see that we were able to grow the scripts despite the major change. Quarter-on-quarter, revenues on Solosec have gone up 48% or so, scripts have gone up 4%. So given the pricing change, there was some impact on growth, but we were pleased that we didn't see a drop. We expect to continue to see this ramp up.
- Neha Manpuria:** And any update on how we plan to augment the pipeline?
- Vinita Gupta:** We are working on multiple opportunities on the specialty front. Ideally, we are looking for opportunities that can help us add to our revenues and margins and be able to leverage our commercial infrastructure. We're working on a number of opportunities. Actually, we have recently brought in a very strong leader in corporate development, who joined us from AMAG, Alan Butcher. So have multiple opportunities that we are working on to help us grow the portfolio.
- Moderator:** Thank you. Next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** First question on FDA. So we have seen more facilities coming into the FDA. Obviously, inspection is part and parcel, but we've been receiving lot of OAI's. So what is the game plan for the next 12 months? Are we on track to get at least 1 out of the bag, which was mentioned in the last call? If you could just help with the update, please.
- Nilesh Gupta:** . We are obviously not happy with where we stand on the compliance front. One of the initiatives that I talked about was a much deeper transformation, a much deeper quality transformation that



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we have started at our Indore site. Again, that is our biggest solution over time, that I think it addresses everything that you can think of. Obviously, investigations to start with, which is a relatively hot button for Lupin and the industry, but also areas like training, SOP simplification. We've made very good progress at our Indore site, where we have piloted this program. The program is basically scheduled to complete by March. We are now starting to roll out the program to our other sites. And specifically, there's a rollout to Goa next week. The intention really is, especially at a site like Goa and our Somerset site to work for the next 2, 3 months on some of these remediation efforts so that we feel really good about the status of these sites. There's a lot of stuff we've already started, but we want to do a concentrated piece of work for the next 3 months and then offer them up for reinspection. So, Goa and Somerset in the course of the next 3 months, the hope would be to go back to FDA and offer them up for reinspection. As we had shared before, the FDA is okay with us putting up one site at a time rather than as you know, Goa and Pithampur were under one warning letter. We don't have to do both sites together. We're going to offer one site at a time, get them ready, make sure that we feel really good about these sites. It's been long. We are not happy about the fact it's been multiple sites. We are not happy about that also. But we have a really clear plan at this point of time. We've also strengthened our team significantly. We've talked in the past about hiring a Head of Compliance, a Head of Investigations, but we've also made a lot of efforts. We've got Johnny Mikell to head our quality and compliance function. He is based in the U.S., but he is spending all his time in India, of course. But we are also augmenting the capabilities of the team further because the more we do this, the more we realize that at each site, manufacturing and quality is where you need the right solid positions. I mean, wherever we find weaknesses, we are augmenting those. There are 2 or 3 sites, where we've already done those. There are a couple of more sites where we still want to address that as well. So that quality is sustainably built into the products that we make. This is a lot of good positive stuff. Obviously, we feel very energized about that. Obviously, none of it is reflected in outcomes at this point of time, but the plan is in the next 3 months to go back to FDA and basically, in the next 6 months, come back to you guys to report good news on this.

**Prakash Agarwal:** So Goa and Somerset more or less in line or on track with the next 3 months completing remediation and calling it for a FDA is what you are saying?

**Nilesh Gupta:** Correct.

**Prakash Agarwal:** But you didn't cover the second piece, which was like more facilities coming under fray. And I'm sure you must have spoken to FDA like or is it system-wide issue, company-wide issue, what's happening? So that piece, if you could help us what is FDA thinking about it? Have you had a conversation already?

**Nilesh Gupta:** We have not specifically spoken to the FDA about the other sites. I believe that the issues at the other sites are specific to those sites. But certainly, we need to have a conversation with FDA on Tarapur, for example. On the other sites, we believe that we can address the observations to the





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agency's satisfaction and with that, we would hope to obviously close this. I don't see this as a company-wide issue, but I do see issues like investigations as something that we want to address across the company. We need to do much better. Again, like I said, the more 483s you see, the more you see that this is an industry issue. But specifically, Lupin has to address it. We need to get our house in order on this count. On these investigations, in particular, there is a lot of stuff that we have put in place. There's a lot more that we're doing as well. Again, part of the work in the next 3 months, will be to complete certain assessments as a mix of internal and external that would give FDA confidence when they were to come in.

**Prakash Agarwal:**

Okay, fair enough. And if you could just update on Gavis, like what part of the amount that we paid is actually now impaired? And what part is sitting on the books? And if there's any large asset that we see from a product pipeline perspective to play out in the next 2, 3 years?

**Vinita Gupta:**

Yes, what is sitting on the books now, Prakash, are really US\$ 200 million or so - US\$ 100 million in IP and US\$ 100 million in goodwill.., The kind of IPs we took impairment on, the largest part of it was Methergine-related life cycle management that didn't make sense any longer. A couple of pipeline products that we were pursuing that didn't make sense any longer. They were part of the valuation. So certainly, felt it was prudent to take the impairment on those. In terms of growth drivers, in Gavis and Somerset going forward, we have ramped up the base business, the GI products there. We are building on the controlled substances products that we have recently launched, the KCl products that we have recently launched. In the next couple of years, we see a couple of First-to-File products like Suprep goes off patent in the next couple of years, where we are First-to-File; Nascobal, where we are First-to-File. We expect to get into the market in the next couple of years. Then there's a whole pipeline effort on pretty interesting complex generics out of the site. We have built capabilities to do drug device combinations, rings and IUDs that help both the generic as well as the brand side of the business.

**Prakash Agarwal:**

And just a small one on how to treat Japan. So, I understand that you have supply arrangements, which will continue for a couple of more years. So is it part of the Asia Pacific business, where does it sit?

**Rajiv Pillai:**

That's correct. Prakash, you're interpreting it correct.

**Nilesh Gupta:**

So, there are 3 parts that will continue for the Japan business, there are certain API supplies to Kyowa and to other companies that will continue, there are formulation supplies to Kyowa from our Goa plant. The third is the Etanercept supply. So those 3 parts will continue. But as Rajiv said, it's a part of the APAC.

**Prakash Agarwal:**

Okay. And last one, the Enbrel in EU, is there an update there?

**Nilesh Gupta:**

No update at this point of time, but we are still on track for end of quarter, likely, I think, positive opinion and approval very shortly after. We are on track.



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- Moderator:** Thank you. The next question is from the line of Kunal Dhamesha from SBI Capital Markets. Please go ahead.
- Kunal Dhamesha:** First one, some clarification on U.S. business. Did we see any impact of Tamiflu in this quarter?
- Vinita Gupta:** We saw some Tamiflu in this quarter. We had Tamiflu also in Q2.
- Kunal Dhamesha:** And secondly on Levothyroxine, as you alluded earlier that half of what you expect is already in the business. Is it what you meant? Or will it come in quarter 4?
- Vinita Gupta:** No, I meant, it will come in quarter 4. We started really building share after we got approval against all the RLDs in November. So it really started to ramp up this quarter.
- Nilesh Gupta:** Q4, and then, really, in Q1, the next fiscal is where you see a much more solid ramp up.
- Kunal Dhamesha:** Secondly, on this coronavirus issue, what is our integration level in terms of API? In terms of product portfolio, how much proportion is integrated? And what are you seeing in terms of price hikes or supply disruption?
- Nilesh Gupta:** Sure. we'll take it in 2 parts. As far as the supply continuity is concerned, we basically buy only a couple of APIs from China, and we certainly buy some intermediates specifically for the cephalosporin antibiotics from China. Based on the inventories and what we have in WIP, we don't see a disruption in this quarter if the situation sorts out in the next few weeks. Right now, unfortunately, there is no visibility. We are not getting visibility on shipment of containers or the like. Obviously, the country is in the state of lock down. But from our perspective, if this gets eased out in the next 3, 4 weeks, we don't see an issue, and we will be able to manage without any significant disruption at all.
- Kunal Dhamesha:** Is it eased out in 3, 4 quarters or 3, 4 months?
- Nilesh Gupta:** I said 3, 4 weeks, actually. So yes, if it's 3, 4 months, definitely, there would be disruption on some of the APIs, especially for ROW geographies like our cephalosporins because Pen-G is one of the key supplies that everybody buys from China. And there isn't an ability to respond to such kind of acute shortages very quickly. So obviously, we are expecting a sooner rather than later solution on some of these things. Right now, we are good on supplies, but obviously it won't continue indefinitely.
- Moderator:** Thank you. Next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.
- Chirag Dagli:** Yes, sir. In terms of Solosec spends above the EBITDA line, if you can split roughly, a large part of this, it's in the staff cost? Or is there a fair amount on the other expense line item as well?



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**Vinita Gupta:** It will be across the lines. But yes, staff cost as well as SG&A.

**Chirag Dagli:** Is it equally split, ma'am, between the 2 line items?

**Nilesh Gupta:** I think we'll have to cull it out separately and get back to you.

**Arvind Bothra:** Chirag, I'll get back to you offline.

**Chirag Dagli:** Okay. I guess, all I'm trying to understand is that, is there a significant amount of promotional spend, which is sitting in the other expenses line item, which may necessarily not recur to this extent?

**Rajiv Pillai:** Chirag, yes, in the other expenses that I called out, one of the items was selling and promotion expenses, but that's not necessarily only in the U.S. in Solosec...

**Nilesh Gupta:** Its more India-centric. Typically, you find that Q2 and especially Q3, you find there's a lot of ad-promotion in this region. Especially India runs higher, and then it comes down in Q4. So, it's not specific to the U.S. as far as the SG&A increase is concerned.

**Vinita Gupta:** Yes, so there's been no change in SG&A for Solosec quarter-on-quarter.

**Rajiv Pillai:** It's consistent.

**Chirag Dagli:** Okay. Fair point. And can you sort of roughly call out the Kyowa impact on the raw material, staff cost and other expense line item? You've articulated the sales piece as well as the overall profitability impact. But just on the individual line items, if you can?

**Nilesh Gupta:** Chirag, we haven't called it out. We've called out only the PBT and PAT.

**Moderator:** Thank you. Next question is from the line of Anubhav Agarwal from Crédit Suisse. Please go ahead.

**Anubhav Agarwal:** My first question was on the pending ANDAs. We have 150-plus pending ANDAs. Can you just help very roughly that from facilities which are clear right now, out of this 150 how many pending ANDAs are really pending?

**Nilesh Gupta:** Anubhav, we don't have an exact split right now, but the largest number would be from Nagpur, followed by, I believe, Indore Unit 2 and then Somerset, Goa is basically in the 20-odd kind of number.

**Anubhav Agarwal:** So Nagpur unit will be taking APIs from the Vizag facility or from the Tarapur facility?



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- Nilesh Gupta:** It would be a mix. The newer ones would be from Vizag and the older ones would be from Tarapur, but we also have Dabhasa. A lot of the APIs would come from Dabhasa as well.
- Anubhav Agarwal:** Okay. To simplify how many launches you're looking to do next year, assuming we don't get clarity on any of the facilities that we have adverse life right now?
- Vinita Gupta:** We have 15-plus launches that we are expecting, Anubhav. There are few that are major, but 15-plus without assuming any clearance of these sites. Then we'll have an upside, if we can clear Goa and Somerset, it could be close to 30.
- Anubhav Agarwal:** Okay. And in this 15, are you already expecting albuterol. So what's timeline you are expecting for albuterol?
- Vinita Gupta:** We're expecting albuterol as part of the 15, and we are hoping that for the top of the fiscal year, we get approval. And we have responded to the FDA in November and have had some communication back and forth. We hope to get approval first half of the fiscal year.
- Anubhav Agarwal:** That's helpful. Now just one question that in the U.S., sales this quarter, we had flattish sales sequentially, now we did have Levo ramp-up market share, not substantially, but at least 1% market share ramp-up is we saw. Seasonally, sales was stronger, some Tamiflu was there. Why it was flattish sequentially?
- Vinita Gupta:** So actually, we didn't have much in terms of ramp-up of share in Levo. We really saw our share pickup at the end of the quarter. So really started to see the impact in January in terms of revenues. And the flu season products, I think we had impact both in Q2 as well as Q3. A number of our customers start stocking up for flu season in August, September.
- Nilesh Gupta:** And Tamiflu was basically flat between Q2 and Q3.
- Vinita Gupta:** That's right.
- Moderator:** Thank you. Next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin Agarwal:** Sir, on the U.S., now, Vinita, how are we looking at the U.S. business? Because in the changed dynamics, when you look at the peer set, people are kind of tweaking their strategies. Either people are looking to go more towards a volume-oriented play or be little more focused towards specialty, I mean, towards fewer but high-value assets. How are we looking at U.S. from a slightly long-term perspective, from a U.S. generic perspective for ourselves?
- Vinita Gupta:** Few areas that we are focusing on. One, we started our whole journey on complex generics a couple of years ago and believe that we are at the cusp now of bringing a number of these products to market, starting with the inhalation products in the next year. We feel on the base



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business, which has, of course gone through a lot of pressures over the last couple of years, there has been a fair degree of stabilization at this point. So, feel pretty good about the base business that we have on the generic front, especially 25 products where we have a very strong position from a vertical integration standpoint as well as market share. We feel pretty good about growing our base business itself based on the position that we have created as well as the supply chain agility that we have built in. And then, I mean, the material growth drivers are really going to be the complex generics, starting with inhalation, albuterol next fiscal year, and then into biosimilars, Pegfilgrastim and Spiriva in the following fiscal year. So, it's a combination of building on the strong foundation that we have in the base business and implementing the complex generic products on the generic side of the business.

**Nitin Agarwal:**

Vinita, on the base business, we have seen there have been multiple companies in the sector who have sort of benefited a whole lot from the shortage situation, which the sector has been throwing up in the U.S. We don't seem to have gained much, despite we having as you mentioned, a reasonably large base portfolio. Is there any particular reason which has prevented us from...

**Vinita Gupta:**

Actually, we have, not in this particular quarter, but if you look in the last 4 quarters, we have picked up share in our base business in the older products, wherever we had the opportunity. We again, picked up position in products where we could supply long term and not just gain from short-term opportunities, short-term windows. We have actually grown our share over the last 4 quarters.

**Moderator:**

Thank you. Next question is from the line of Aditya Khemka from DSP Blackrock. Please go ahead.

**Aditya Khemka:**

Could you just talk a bit about the domestic business. I mean, looking at your pure revenues and growth etc., this quarter seemed to be a little **good** for the market overall, whereas our revenue seems to have grown only 9%. So what is it exactly that we are facing as a challenge in the business?

**Nilesh Gupta:**

The India formulation sales includes some of the tender business that we take as well, but if you take the pure India branded formulations that grew by 10.6% in this quarter. We feel very good, we've always talked about 12% to 14% growth. We feel good about the number. It's come down probably 1% or 2% from what we had originally guided and that's a function of GDP as well. There is a lot of exciting stuff that we're doing in India. As we did our budget a couple of days ago, it almost sounded like a strategy exercise because that's the number of things that we're doing in India. Just in the last year, we launched 3 new divisions. There's one more division that we are launching this quarter. We are adding people as well. There are a whole bunch of initiatives around patients, around doctors, around just the relationship management as well. Lot more analytics are now starting to get available in India, which were never available before. One of the things that we're rolling out in the next 6 months is a real effort versus return kind of assessment on an ongoing live basis. We've never had that. We've worked in the same way as



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we worked for many years so far in India. A lot of that is changing. So very excited about India. The reach is increasing as well in terms of the representatives that we are adding. We are using areas like telemarketing to reach a wider populous. In areas like inhalation, in diabetes, in cardiovascular, we have the best portfolios that you could imagine. I don't think anybody, for example, in diabetes has a better portfolio than Lupin does and there's a lot of room to grow. It's still a very fragmented market. The Lupin story is going to be about, obviously, enjoying the market growth rate, but also taking market share. I think that's something that we've done. In the course of the last 5 years, in the top 300, we had 2 products, we've moved to 9. We were #9, we have moved to #6 and there's a lot more room to grow in this market. There are a bunch of measures that we have for growth. And a lot of them also start falling into the domain of providing health care services, not just pure pharmaceutical.

**Aditya Khemka:**

Great. So could you quantify what percentage of our revenue comes from tenders? And are these tenders like state and government tenders? Or are these like those state-generic tenders that you get from certain players?

**Nilesh Gupta:**

I think the only part we need to call out there is the global institution business that we do, which gets sold in India as well. That's the one which comes into the numbers. Then the lion's share of this is the India business. But typically, there's lumpiness around the tenders. Now we fold the OTC business that we have into this as well. That's a single-digit kind of growth. Specifically, in this quarter, the tender part, actually, de-grew. So, it brings the numbers down. But the India-branded business is the number that we keep tracking closely. Like I said, that is firmly in the 10-plus percent range.

**Aditya Khemka:**

And just a query on the overall margin profile. So I mean, there have been a few questions on this. But even if you include your other income, the margin profile of 14% EBITDA, if you benchmark it against some of the companies of your size and profile seems to be extremely depressed. And now we don't have the luxury of larger products in U.S. like we used to have the metformin franchise etc. and you have, in the past, spoken of your cost initiatives, but it doesn't seem to reflect in the numbers, right? So what are the timelines that you as management are running with about achieving those cost objectives, so that 18% EBITDA margin that we keep talking about, 18% to 20% EBITDA, even that number isn't really close to the benchmark that the rest of the industry of your size operates. So where are we really lagging when it comes to EBITDA?

**Nilesh Gupta:**

So maybe I can answer, Vinita can add and why are we at 18% to 20%. First of all, we are seeing tepid growth in markets like U.S., specifically in the U.S. generics front. We are investing heavily in specialty, so there's a full burn rate going on Solosec. And we are investing ahead of the curve on R&D. As you've seen on R&D, our spend is amongst the highest. Why is it the highest? It's because we have multiple bets on inhalation, we have complex injectables and we have a few select biosimilars going on as well. We feel very good about our portfolio. We feel very good about the R&D that we are doing. Obviously, we are very cognizant of the Solosec



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burn and - we are very attuned. Part of the things that Vinita talked about even in the last 3 months was a new leadership team, a new head that we brought in for the specialty business, people like Alan that we brought in on the corporate development side are also extremely strong on the specialty side. And obviously, our focus is on building that part of the business. There's more than commensurate burn happening on the specialty side. - Generics is at a low as far as the profitability is concerned because of the R&D spend that goes into that business as well, obviously, by itself. And if you were not to spend the R&D, there's a very high level of profitability. So - that is a function of the R&D spend that we are doing. These I would call out as the big elements. As we look and as we go forward, we obviously expect growth in generics. So not just in the complex generics, but in oral solids as well, we expect growth in the next 1 year, 2 years. We see the inhalation portfolio starting from next year, not just in the U.S., but products like Fostair in Europe as well. We see injectables, we've launched the first of our injectable in December, obviously, it's small, but again, the intent would be to build it forward. And we've still not delivered from areas like Nanomi, we are very happy with some of the progress we've made, but we still need to make filings, get approvals. So, there's a lot of stuff that we are investing in right now, which we are not getting return on. But we could optimize that to make sure that if we were to bring that R&D percentage down by 3% or 4%, that will go to the EBITDA line. But we'll be cutting our long-term future short. We see inhalation as a major growth driver in the future. We see biosimilars, even though we are only taking select opportunities, but we see biosimilars as a very solid growth driver as well. And on the third level, the injectables. We feel good about specialty, right, but we are also cognizant of the fact of the burn. We're obviously looking at what is the best way to optimize that as well. So that's the reason why we always said that we'll stay at this 18%, 20%. The idea would be to basically improve by 1 or 2 percentage points each year, especially as the business takes off again, specifically U.S. generics and the specialty.

**Aditya Khemka:** Right. And these 4 other regions that we have APAC, EMEA, LATAM and ROW, just to get a sense on the overheads. How many of these 4 regions do we have our own personal foot soldiers promoting our product?

**Nilesh Gupta:** In all these regions. Let's just start with APAC, in Australia and Philippines, we have our own onshore presence. Japan, obviously, was known. As far as EMEA is concerned, particularly U.K. and Germany and then South Africa and then in LATAM, Brazil and Mexico.

**Aditya Khemka:** Okay. So you have your own foot soldiers in all of these regions basically.

**Nilesh Gupta:** And the other part in North America- Canada, we have our own team as well. We always called ourselves a transnational company. The idea was to go deep in select markets rather than go wide across.



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- Aditya Khemka:** Fair enough. Just one last question, if I may. On the number of MRs. So could you give me a sense of how many MRs you have in India? And what's the sort of trajectory that you expect there for the next 2 years?
- Nilesh Gupta:** About 5,500 medical representatives, but if you take the entire sales team, it's more than 7,000. And the intention is to add anywhere from 300 to 500 each year.
- Moderator:** Thank you. We take the next question from the line of Anmol Ganjoo from JM Financial. Please go ahead.
- Anmol:** My question is to Vinita. Vinita, you spoke about we reaching an inflection point where a lot of our complex generic initiatives come to fruition. How vulnerable are some of the assets to the regulatory situation currently? I mean, as we move closer to monetization, what do you worry about the most in terms of either an asset or a facility? And what are the vulnerabilities in the path of commercialization or monetization of these? Anything you want to call out would be...
- Vinita Gupta:** I mean, they vary by platform. Obviously, some are more proven than others. Inhalation is a big bet for us. We believe that the agency is very keen on getting products to the finish line. But we have to still traverse that path. We have to get product approvals to start monetizing it. Obviously, we are working very closely with the agency to make that happen. You mentioned facility, of course, is make or break. We are very cognizant of that as well. But as we look at some of these areas right now in the near term, you look at inhalation, which is important part of our growth driver in the next couple of years. And specifically look at the product filings, whether it's albuterol in the U.S., Fostair in Europe, Spiriva in the U.S. and the facilities they are from like Pithampur Unit 3, which has gone through FDA inspection, gone through European inspections, and we feel good about the ability to get approved for these products and supply out of there. Likewise, on the biosimilars front, which, again, is a material growth driver in the next couple of years, we have received approval in Japan, we have received approval in Australia. Expect that we should be able to get product approval also in Europe and then U.S., of course, for pegfilgrastim and other products in the future. Over the last couple of years, there have been a lot of learnings along the way. As we get closer to this point, we feel good about our ability to be able to monetize this investment and this pipeline over the next few years.
- Anmol:** That's helpful. And my second question is to Vinita. Sorry, if I sound repetitive, but ending this year with an 18% EBITDA margin and then looking north from there, we'll have some implicit assumptions in terms of operating leverage coming through or some of the remediation cost going away, regulatory situation at some of the sites improving, some of the markets picking up and some cost being taken out structurally. So if you could just probably call out some of these drivers, so which take us back to 18%-plus margins on a sustainable basis that will be really helpful because as of now, I'm not saying that you guys won't be able to do it, but it doesn't look that easy.





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- Vinita Gupta:** Nilesh, of course shared earlier and I will just add to it. If you look at the full year this year, we have achieved 18.5% so far, and we expect to be at that 18% or so level. It's really based on no material product addition so far. I mean, we'd hoped to get a good part of Levo into the year, we'd hoped to get albuterol in the year. But Levo is ramping up only now, albuterol is delayed. Solosec has taken a little bit longer. Obviously, if you look at the year, at least from one of the major growth driver, the U.S. and the major products from the U.S., we've had a few delays and are starting to see the benefits of these in the current quarter and the quarters to come. So that is on the one side. The second area is cost optimization efforts, which we've been working pretty hard over the last 1.5 years. We'll have some impact again in this quarter, but it's really a more material impact in the next fiscal year. It's a combination of really executing on our pipeline on the generic front and getting operating leverage on the specialty front as well as driving cost optimization.
- Nilesh Gupta:** Just to summarize, the Solosec burn will come down in the next year, the generic profitability will go up in the next year. India profitability will go up in the next year. R&D will basically stay flattish and then obviously, the cost optimization measures will kick in as well. It will still probably stay in the 18%, 20% for the next fiscal, but hopefully, at the higher end of that. And then we'll obviously take it thereafter.
- Arvind Bothra:** Also, just to clarify, the 18% to 20% that we are looking at is on operational basis. As you understand, the current year's base also includes income from AbbVie licensing
- Moderator:** Thank you. Next question is from the line of Prashant Nair from Citigroup. Please go ahead.
- Prashant Nair:** Just a couple of small questions. So firstly, what would your effective tax rate be now that the intangibles are off the book going forward, where should we see that settling down?
- Rajiv Pillai:** During the course of the year, we had talked of in the mid-40s or 44%, 45%. I expect that by the end of the year, it will still be in that range or it will be in the 44%, 45% range. But for the next year, it will be less than 40%.
- Prashant Nair:** Okay. And just the second question, can you break down this quarter's U.S. revenues between generics and branded?
- Rajiv Pillai:** We are doing about, like I said, around US\$182 million around on generics and brand was about US\$4.5 million.
- Moderator:** Thank you. Next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.
- Dheeresh Pathak:** Just continuing with what other participants have highlighted and also what you've been articulating towards that cost optimization measures and we are not seeing that benefit. For



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instance, in this quarter, when you are restating your numbers for the Kyowa divestment, you lost the sales and the gross profits associated with that business, but the other expense that should have gone down because of that business, you are not seeing that benefit in other expenses. If you look at your September '19 and June '19 other expense, it is at a much lower level versus what you are reporting for the December quarter. If you just work it out based on numbers which you are highlighting, at least Rs.120 crores of quarterly other expense reduction should have been there just because of the Kyowa divestment. I mean, R&D is not sequentially up that much. So remediation and promotional, can you just explain that why are we not seeing for efforts...

- Rajiv Pillai:** I'll explain. So, you are looking at the Rs.1,220 crores versus Rs.1,240 crores, is that...
- Nilesh Gupta:** No, he was looking at the numbers, pre-restatement and post restatement after Kyowa. Kyowa goes through all the lines, so it's difficult to call out. I don't think there was Rs.120 crores worth of expenses quarterly being carried in Lupin on the Kyowa account. But that's some of the restatement lines with that.
- Rajiv Pillai:** Like we said, Rs.1,137crores to Rs.1,240 crores because if you are looking at sequentially, that number is standing out. That is on account of restatement. Rs.1,137 crores looks lower, and that's why the delta looks much higher. But yes, like we said, this quarter has got lumpiness on account of both sales promotion, higher sales promotion activity in some of the branded generic markets and a higher investment in R&D and the one-offs on the remediation, which we believe will go away in the near future. So Rs.1,240 crores is not the number, which is a reference point. It is Rs.1,200 crores, it would be lower
- Dheeresh Pathak:** Sorry, sequentially R&D has not gone up, why are you calling out R&D as a reason for higher other expense sequentially?
- Rajiv Pillai:** Let me clarify. So, the number that you are seeing, Rs.435 crores and that thing you are comparing that with the Rs.422 crores, but that included Kyowa, right? So Rs.422 crores that you are seeing now excludes Kyowa. So, on a comparable basis, R&D has gone up.
- Dheeresh Pathak:** What was the comparable R&D expense for the September quarter?
- Rajiv Pillai:** Rs. 20 plus crores. It will be more than Rs. 20 crores, closer to Rs. 25-odd crores.
- Dheeresh Pathak:** You should also give us some milestones that you are looking to achieve in your specialty business and a timeframe that you are looking to achieve them, beyond which then you need to, like, for example, Gavis, you are writing off, right? And at the time of acquisition, we had obviously times changed, but for Solosec and other specialty, where you are investing in, at least as shareholders, we should understand what milestones and in what timeframe you want to achieve them, after which then you should have a critical evaluation of whether that money is being well spent.



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- Vinita Gupta:** At this point, we really consider it really a launch phase, still in the first 2 years. We are seeing some silver lining from the efforts that we have made, especially the recent changes over the last 3 to 6 months. To really take the current run rate as an indicator of what the product is likely to do will be incorrect. We are fairly committed to building a specialty business. Obviously, our very objective in making sure that month-after-month, quarter-after-quarter, we see improvements and are working towards it. At the end of the day, if we don't see that our promotion efforts have the right response, obviously, we will start optimizing the P&L wherever it makes sense. But at this point in time, we are seeing promotion responsiveness from the reps as well as the other promotion efforts that we are making. We continue to believe that we'll be able to grow the product to a good scale to help build our women's health business.
- Moderator:** Thank you. We take the last question from the line of Krishnendu Saha from Quantum Mutual Fund. Please go ahead.
- Krishnendu Saha:** Just a broad question on the U.S. plant issues and all. Just to understand, if we get the approval to launch 30 products. So on that note, for the last 2 years, how much have we spent? And how much opportunity lost for us has been there, could you just quantify for that? And how much in the Indian revenue is for the DPCO related?
- Nilesh Gupta:** The opportunity loss is quite in line with what we talked, basically, it's about US\$40 - US\$50 million a year from the 2 facilities. That remains the number because I don't think we are talking about day 1 or day 181, launches getting impacted. We are just talking about good, regular, oral solid products that have got held back on account of the compliance issues. We haven't talked separately about the remediation efforts, but those expenses, while they are lumpy in this quarter, year-on-year, they are actually down. Those expenses are actually on the decline.
- Krishnendu Saha:** Last 2, 3 years, how much would you spend US\$100 million, US\$50 million?
- Nilesh Gupta:** No, I wouldn't throw a number out like that. But it's too many lines that this kind of stuff would go into. What was your question on the DPCO?
- Krishnendu Saha:** How is the Indian revenue in the DPCO right now?
- Nilesh Gupta:** About 23% of our products are controlled right now.
- Krishnendu Saha:** And Nilesh, one more question on understanding the Indian front, we've got a high number of in-licensing products for the Indian business like 40, 45, if I'm not mistaken, like, I could be off a couple of. So our strategy over there is to keep on building that pipeline. And what therapy focus is, how do we capture or retain the market share over there, sir, a little bit of more especially on the Indian side, if you can give us?



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- Nilesh Gupta:** Sure. On the India part, obviously, we've taken a lot of pride in building our in-license portfolio. That's not at the cost of building our own portfolio. One of the things that we identified in the last 2 years was to build out a lot more of our own portfolio as well. You want to get the best of both worlds. You want to be able to do the in-license products, but you also want to be able to maximize the offering of products that you could do yourself. We've not done a good job of that in the past, but we've started working on that now. Obviously, as patent expiries hit and different other products are an opportunity to launch, we try to maximize our chances on that as well. We would do that as much as possible. We found that innovator companies are actually quite reasonable when it comes to that as long as we are doing adequate justice to their portfolio. But in-license will remain an important part of our business, but a lot of it was through the diabetes and cardiovascular products that we launched over the last 3 years. Going forward, we see in-license as important, but we don't see that many big products in these categories. We would see oncology products, we would see specific products, but we wouldn't see that much of these big in-license products. Those we would expect to make up from our own pipeline.
- Krishnendu Saha:** How much do you expect the volume growth for us for the Indian business?
- Nilesh Gupta:** So the volume growth is usually about 3% or 4%. On top of that is the new launches that we do, and the rest of it comes out of price increases.
- Krishnendu Saha:** And last question from my side, the in-licensing, AbbVie, we got, what is the timeline for the next opportunity for us over there? Any timeline over there? The in-licensing income which we got last year.
- Nilesh Gupta:** The licensing income, we don't see a milestone in this current fiscal, in FY '21. The next milestone we see would be in FY '22. Both of those projects are moving along nicely. We have regular reviews, which have started as well. But just in the nature of the development, we don't see anything in FY '21. We see the next milestone in FY '22.
- Krishnendu Saha:** And how big could that '22 be number? What is the significance of '22 in the whole scheme of things?
- Nilesh Gupta:** There will be a significant number. Again, we've not called it out as a specific one, and really no sense in talking about it till we hit that milestone. Obviously, we'd love to come and talk about it when we do.
- Moderator:** Thank you. Sir, you may please go ahead with your closing remarks.
- Dr. Kamal Sharma:** Thank you, everyone. I hope your questions were well answered. Just in case you have some residual doubts in your mind, you could contact Arvind or Rajiv to get your questions sorted out and look forward to seeing you again next quarter. So thank you, and good luck.



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**Vinita Gupta:**

Thank you.

**Moderator:**

Thank you. On behalf of Lupin Limited, that concludes this conference. Thank you for joining us. You may now disconnect your lines.