“Lupin Limited Q3 FY2023 Earnings Conference Call”

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MANAGEMENT:

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Moderator: Welcome to Lupin Limited Q3 FY23 Earnings Conference Call. Please note that all participant lines will be in listen-only mode. And there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded.

I now hand the conference over to the management. Thank you, and over to you.

Vinita Gupta: Thank you. Good afternoon, friends. I'm very pleased to welcome you to our Q3 earnings call. I have with me our Managing Director, Nilesh as well as our CFO, Ramesh. As you would have noted, we have continued to build on our momentum in Q3, both on revenues and in particular, on margins. I'm very pleased that in Q3, our US business performed well, India business growth improved, and API business rebounded as well.

On the margin front, we saw the benefit of NPLs in the US, seasonal product upside as well, and continued savings from our optimization measures. We are focused on sustaining this positive momentum, in particular as material new product launches start and our recent investment in our sales force expansion in India starts yielding results.

I will let Ramesh talk through the performance in deeper detail. I would like to share some of the business highlights.

In the US, we have continued to evolve our business with optimization of oral solids, driving growth of complex generics, respiratory franchise in particular, and executing on our new product launches. During the quarter, our in-line business was almost flat with slight decline due to exit from low-margin products, offset almost completely by seasonal products.

New product launches in the year contributed well in the quarter, with Suprep ramping up, Perforomist generic successful launch and then Pennsaid authorized generic launch. Our respiratory franchise strengthened with albuterol continued strong performance, addition of Brovana and Xopenex brands as well as generics launch.

As we look at the quarters ahead, we expect new product launches like gSpiriva, gDiazepam Gel, gNascobal Nasal Spray and gDarunavir, all products where we have either exclusivity or first to market position, which will drive growth of our US business in a profitable manner. On Spiriva, we continue to make progress and have received priority review from the FDA for a target action date in April, without inspection, or July, with inspection. In the meantime, we are getting ready with launch preparedness. We continue to see Tiotropium as a substantial opportunity for fiscal year '24 with a significant runway, given the competitive dynamics.

Products like gDiazepam Gel and gNascobal, we now hope to see approval soon given the recent successful Somerset audit. Our US generics business has come a long way in calendar year '22, still a long way to go. However, with the

new product launches coming in, continued optimization efforts, focused efforts on building a niche inhalation, as well as injectables pipeline, we are optimistic that we will grow our US business in the next couple of years.

Switching to India, the largest part of our business, while our growth in the quarter and first half has been below market, this is primarily due to loss of Cidmus from a cardiovascular portfolio and genericization in the diabetes segment in the gliptins. But for the diabetes portfolio, our growth in Q3 was in line with market, with therapeutic areas like cardiac, GI, respiratory, all delivering double-digit growth. Our gynaecology and GI have actually been the fastest growth therapeutic areas for us. This quarter, we have added close to a 1,000 reps, created six new divisions to expand our reach and share of wallets. We expect the investments to get us to above market growth in the quarters ahead. We are committed to growing our India business to double-digit growth in the quarters ahead.

Other than India and the US, our API business recovered with the growth in cephalosporins and other countries like UK on the back of Fostair generic and Germany due to NaMuscula grew as well quarter-over-quarter. On the margin front, we expect continued improvement in particular as we execute on new product launches and our recent investment in the sales force in India starts yielding results. Likewise, we continue to focus on cost optimization efforts. While we have been successful in optimizing our manpower costs, we have been very disciplined in getting out of low margin products that has not allowed us to optimize our idle costs. Nevertheless, we are confident with the efforts that we have underway, we should be able to move the needle on this front in the quarters to come as well.

On the compliance front, we have made progress with positive outcomes on sites like Ankleshwar, Nagpur injectables and Somerset. We've also made substantial progress on our remediation efforts in Tarapur and Mandideep. The recent approval of our injectables facility will enable us to start building our organic injectables portfolio in full earnest. Overall, we are moving in the right direction. We expect the pace to get better, as we execute on our material new product launches in the quarters ahead.

With this, I will hand it over to Ramesh for deeper analysis of our performance.

Ramesh Swaminathan: Thank you, Vinita, and good afternoon, friends. Sales for the current quarter were INR4,244 crores as compared to INR4,091 crores in Q2 FY23, a growth of 3.7%. On a year on year basis, the growth was 3.8% while the previous year sales was INR4,087 crores.

The US business -- in the quarter, the US business registered a 11.2% growth in local currency terms on quarter-on-quarter basis with new product launches in the US generics business and brands acquired from Sunovion. On a year-on-year basis, revenue declined by 12.3% in local terms with price erosion in top brands like Brovana, Albuterol and Famotidine. We launched four new

products: Perforomist, Pennsaid, Rufinamide, and Paliperidone ER tablets in Q3 FY23, bringing the total NPLs to 8 for the year. NPLs contributed $20 million in Q3 revenue.

India branded formulations business declined by 3.4% in Q3 versus Q2, whilst on year-on-year basis, sales grew by 2.6%. The overall market growth during Q3 was 10%, whilst Lupin grew by 7.5%. Loss of exclusivity and genericization in the anti-diabetic's portfolio has impacted growth rate of Lupin. Inlicensed portfolio held by Lupin in the anti-diabetes is close to 55% of the portfolio for anti-diabetes portfolio. As you would know, our top three TAs are cardiovascular, diabetes, and respiratory. Apart from that, gynaecology, and GI, we are also doing very well. And they are growing, in the case of gynaecology by 19.7% and GI by 16.1%. API business sales grew by 12.7% quarter on quarter as core cephalosporins API sales recovered during the quarter. Year-on-year basis, sales growth was 9.8%.

On the EMEA front, revenue growth of 11.1% year-on-year basis. strong performance of back Luforbec in UK and NaMuscula in Germany was registered. Sales for Growth Markets grew by 23.5% vis-a-vis Q3 FY22 and declined by 5.9% vis-a-vis the previous quarter.

Gross margins. Q3 FY23 gross margins are 59.8% as compared to 58.1% in the previous quarter. This is mainly due to US margin improvement, better product mix and reduction in freight rates. As compared to Q3 FY23 gross margins, the slight margin is due to reduction in write-offs, freight, offsetting the impact of price erosion in the US markets, and of course, inflationary pressures on the cost front. On the employee benefit front, Q3 FY23 was INR764 crores vis-a-vis INR771 crores in the previous quarter. There is a marginal decline on quarter-on-quarter basis because of star club payments made in the last quarter. We had highlighted this in our last earnings call as well.

On an ongoing basis, we expect employee cost to be in the range of 18.5% to 19% of sales, as we build our sales force in India and Vinita just spoke about that. A lot of people have been asking about our "manufacturing and other expenses" spend. There is indeed a one-time expenditure base increase by about INR40 crores which will potentially come down next quarter, but that also perhaps in some base we offset by perhaps an R&D increase next quarter.

EBITDA margins: Operating EBITDA excluding FX and other income is 12.2% in Q3, a quarter-on-quarter growth by 160 basis points because of higher sales, gross margins and cost control. Normalized ETR is expected to be 35% as a few subsidiaries like LI, LOI, Digital and Healthcare continued to have losses. On the balance sheet front, there has been lot of optimization that we've been working on and working capital operating days were lower by five working days.

With this may I have the pleasure of opening this floor for discussion?

Moderator: Yes. Thank you very much. We will now begin the question-and-answer session.

So, the first question is from Prakash.

Prakash Agarwal: Yeah, hi. Good afternoon. Just wanted to check on the US run rate. We had fairly good launches where we have couple of -- one AG and recent launches and we also acquired the two decent sized products. Just wanted to understand and the season of -- season was also good. I think the flu season was good. Other companies have reported market share gains. Would you -- were you satisfied with the US performance or we missed some contracts or how to think about it as a base business now?

Vinita Gupta: No, we were satisfied with the performance, Prakash. On the one hand, we should never be satisfied with the performance, but it's come a long way in the last couple of quarters, the business, both the base business, in-line business as well as new product launches have contributed very nicely to the quarter. I'd say that the impact of the flu season products, that obviously as the flu season recedes, which has already started, one will see some decline on that front. But the team continues to work on this. Now the 170 plus million dollars run rate with the current products until we can get additional new product launches like Tiotropium and the like.

Prakash Agarwal: Okay. I mean, so it's a full quarter benefits of these launches as well as the acquired assets is what I was trying to understand and you are saying that, yes, it had full quarter benefits.

Vinita Gupta: No, I won't say it's full quarter benefits, because we had the brands for two months, Xopenex and Brovana. And Perforomist, we had some upside opportunity that we were able to capitalize on, because of supply issues of some of our competitors. So I would say, we will see an increase from the brand products, but we'll probably see a normalization on Perforomist.

Prakash Agarwal: Okay, got it. Fair enough. And secondly on Spiriva. So, what I heard was April, the TAD date has moved a bit to April, which is with inspection and June without inspection. If you could just give more colour, what does it mean. So TAD date is like what kind -- colour on the queries that has come in and without inspection means that if they don't come by June, it would deemed to be approved or how should we think about that?

Vinita Gupta: So, it's actually the other way around, Prakash. It's April without inspection and July with inspection. So, the FDA decides that they want to come and inspect, then it will -- the TAD date will be July. But if they decide that they don't want to inspect, which is very hard for us to predict, the agency is going to inspect or not, then it's going to likely be April. And we are hopeful that we can expedite it as much as possible, just given that our back and forth with the agency. Majority of the disciplines have been closed. CMC, PD, and disciplines

have been closed. I believe that quality is still pending and that's why I say it's either April or July.

Prakash Agarwal: Okay. And lastly on the cost side, I think Ramesh did mention that there is a INR40 crore one-off, but even if I strip that off, that cost is fairly high. So -- and I understand there's a 1,000 people have been added. So incrementally SG&A, traveling, marketing will increase from here. So first is, why the jump? I mean, apart from normal inflation, is there anything else that has increased or is it maybe forex as well? And how do we see this number moving going ahead?

Ramesh Swaminathan: There is of course a slight impact because of forex because there is a rupee depreciation and when you translate expenses outside the country, it does happen that way. But the large chunk of it is actually coming in because of the fact that you have had higher travel. And I also told you, in Q2, there was a shift to in fact payroll expenses which is shifted back here. To that extent, it has kind of normalized out here. There has been a higher component in terms of litigation spends and the like as well. So, all of this has actually contributed.

Whilst -- your question actually comes in from the fact that what did we do on the optimization plan. I rush to tell you that, we've been doing a lot of work on that. To be honest, a lot of it actually happens at the gross margins line itself and that is in terms of our routes of synthesis, alternate vendor development and the like. But this has also been in some ways eroded by higher inflation out there. Also, there were inefficiencies across various lines. And at the start of the year, we spoke about in fact trying to address the manpower situation at the factory level. We have been pretty successful there and it's captured in some ways in the staff costs cell.

There are other lines where we have been extremely successful. But there are parts which we couldn't do much because the fact that volumes did drop, we had to take write-offs in terms of inventories that we had and plus, of course, issues that we had on the impurities front itself. So whilst the initiatives are still on, there have been mixed results. But you'll certainly see a lot more of this bearing fruit in the quarters to come.

Prakash Agarwal: Okay. So our EBITDA margin guidance of exited of 16 to 18 with cost increasing and Spiriva moving out to next quarter changes, right?

In a sense, yes. So, if you're talking about specifically quarter four, it would be in the same line, in the same range as the current quarter. But once we actually have the top line moving, which will potentially happen once we have Spiriva coming in and of course we've got Darunavir and others, you could expect, in fact, that to obviously impact the bottom line as well. We would continue to work on the cost lines as well. But I think we're really banking on the top line to shift to actually to see a real shift in the -- on the EBITDA front.

Prakash Agarwal: Okay. Lovely. Thank you and all the best.

Moderator: Thank you very much. The next question is from Saion Mukherjee.

Saion Mukherjee: Yeah, hi. So, sir, just to carrying forward the question, I mean, you are banking on top line to deliver the margins, but it's a handful of products. So, you have Spiriva. In case that gets further delayed, what's your outlook on margin in that case? And in that context, it is important to understand in some granular detail, what's the kind of cost control initiatives that the company intends to take, because banking on US revenues and that too with a handful of products, there can be potential risks to that, because the margins are very low at this point?

Ramesh Swaminathan: Yeah. So, I also recognize that. We also recognize that in lots of way, Saion. So if the top line doesn't move, then potentially we still have to work on various initiatives on the cost front. And there are several things which you still can. For example, there is an element of FTS still coming in because of the fact that if there are impurities and we are not able to supply, that's actually impacting in some ways the bottom line itself. There were write-offs that we have taken during the course of this year. So those are lines that we still can work on, apart from, the footprint that we would reduce in case there is a further volume drop. So we would -- so it has to be in some ways an iterative process. We need to kind of weigh the pros and cons of potentially when would the top lines start moving and then potentially work on other items as well.

Specifically when it comes to India region, yes, we are going to add more people, but we're also working on productivity. So whilst there is going to be an increase in overall expenses, we also believe that there is going to be commensurate increase on the top line. So, there would be. So, at the very least, what I do expect is that, if Spiriva and other products are going to get delayed, the expense lines will certainly -- will go down that path in terms of reducing. That could of course shift the EBITDA line in some way; not to the extent that the top line can really move it, but there was certainly a perceptible increase because of the reduction on the expense front itself.

Nilesh Gupta: Would you like to talk about material rates as well.

Ramesh Swaminathan: Yeah. So if we talk about -- there has been an increase in cost of production because of that and which is really impacting in some ways the gross margin line, but better sales mix and of course, reduction in terms of other -- the air freight and others have actually brought in some benefit there and that's reflected in the gross margin increase this time around.

Saion Mukherjee: Yeah. Ramesh, you used to talk about INR500 crores of savings. There was a number which you talked about earlier. is that number still valid and how much have we already achieved and how much is left? If you can give some colour as to how much more just from a cost perspective one can expect?

Ramesh Swaminathan: Yeah. So the INR600 crores really could be broken down into six or seven buckets, so to speak. We achieved a lot of success in at least three or four of them, whilst two others we were kind of stymied because the volumes dropped and there was write-offs among others. So overall, I would say that it's mixed results. So at least about 50% to 60% has been achieved, but where

we have not achieved also just significantly alters the balance. So still working on those. And it's not as it will never get achieved. It will get achieved. It's only a question of time and that would actually kind of round up the full complement.

Saion Mukherjee: Okay. Just one last question. Just a clarification on the new product contribution, $20 million I think you mentioned, this includes the acquired brands and also if you can indicate what's the exposure to the US market from the Mandideep facility in terms of revenues?

Vinita Gupta: The largest part of it is Suprep, Perforomist, Pennsaid and two months' worth of the brands.

Nilesh Gupta: The exposure from Mandideep to US revenues is some 10%, I'm not sure if it's upward of 5%.

Ramesh Swaminathan: Yeah. So, what we really are looking at is only suspensions out there in terms of PenG products

Saion Mukherjee: Okay. Thank you.

Moderator: Thank you very much. The next question is from Damayanti Kerai.

Damayanti Kerai: Okay. Great. Thanks for the opportunity. So, coming back to cost, first few clarifications. So, you added 1,000 people in your India sales team. So when did this addition happen, because sequentially we haven't seen much change in the staff cost. And then you are planning to add on more people. So how many potentially could come in? And when do you expect these new people to start contributing meaningfully? So, what we understand is, it takes around one and a half to two years. So, are you expecting a similar timeframe?

Nilesh Gupta: So, we started adding from November. And in this quarter, we will complete the addition and large part of that is really in this quarter that we're adding. We're creating six new divisions out of that. And part of this is just the fact that we are under-indexed in India as far as our sales force is concerned. So, we will some impact this quarter. But as you know, we've also been growing below the industry average in the last few quarters. And that is changing. So, I already see that minus the in-licensed portfolio, we are already at market growth rate. And even after adding these people, we will see further acceleration of our growth. My expectation is that, from the second quarter, we will be growing overall at a rate faster than the market.

Damayanti Kerai: So, Nilesh, how many people are left to be added. So, 1,000 are done, right, and...

Nilesh Gupta: No, that was the entire number. So, the entire number is largely done.

Damayanti Kerai: Okay. But impact of that is not getting reflected in staff costs, right? What we have seen, it's mostly similar. So, it will be...

Nilesh Gupta: Yeah. So, I think there was some small number which was added in this past quarter. In Q4 is where you will see some impact of the staff cost addition. That also is staggered through the quarter and then it gets baked into the numbers from Q1 onwards.

Damayanti Kerai: Okay. Q1 onwards.

Second, Ramesh, you mentioned fourth quarter -- sorry, third quarter number obviously had one-off and then you are saying, if we move to fourth quarter, that one-off might come down. But you are saying R&D will catch up, because third quarter was bit less. So, should we assume broadly similar other operating expense cost to continue?

Ramesh Swaminathan: Yes, I think -- it will be more or less in the same range. It will come down a little bit in terms of SG&A expense that we can control, but broadly around this. Employee cost go up a little, but that's on a different line.

Damayanti Kerai: So, if I just look at the cost and then we wait for Spiriva and other key approvals to come in, when we should be seeing, I'll say, notable benefits coming from all the efforts, which you have been doing on the cost front for last several years?

Ramesh Swaminathan: So, we were stymied for -- because of reasons beyond our control. These were really about, in some ways, the volumes dropping and because of write-offs and others. And those buckets we would be addressing. So, these are not going to continue forever. These are systemic issues that we kind of faced, which we have addressed. Those will get corrected. So, if you're talking about the total quantum of INR600 crores benefit flowing in, it would have flowed into the P&L by the time we're through with this.

Nilesh Gupta: Just more specifically I think Q2 onwards we would see improvement in performance. We have Darunavir, we had some of this optimization that will kick in as well. That's what we're seeing and obviously, Tiotropium will only further improve that picture.

Damayanti Kerai: Okay. My last question is on India bit. So diabetic portfolio obviously, we have seen genericization. But with more salespeople coming on-board, which segments you're focusing, which could really help you to outpace the market growth in coming few quarters?

Nilesh Gupta: So, our big therapy areas are diabetes, cardiovascular and respiratory. And these are the three areas that would grow as well. So, while it's a point of time, the diabetes market is also bouncing back. In addition, areas like GI, areas like women's health are growing strong double-digit as well and these are areas that we would accelerate as well.

Damayanti Kerai: Just I think one clarification. In diabetes, are we relying more on, say, improved penetration because maybe like there are some new launches lined out, but are you relying more on volume penetration to pick up pace?

Nilesh Gupta: Unfortunately, India is a diabetes capital of the world. So, I think the market potential is always there. Value-wise, it is vitiated at this point of time because of the genericization of multiple products in the diabetes portfolio for the market itself, right. So, it's the only segment that is really growing at best a single digit kind of number in the Indian market. And if it's going to bounce back for the market, it's going to bounce back for us as well.

Damayanti Kerai: Okay. Thank you. I'll get back in the queue.

Moderator: Thank you very much. The next question is from Surya Patra.

Surya Patra: Well, thanks for this opportunity, sir. My first question is on the kind of a potential profitability that we can attain over next one-to-two-year period. So practically, having seen the pricing pressure in one of the key complex products what we have been waiting for, let's say, Albuterol and other respiratory products, so now our focus has been obviously on the complex generics and we have been spending a lot. But we are also visualizing that or seeing the kind of pricing pressure, as well as competition, on the complex products are also witnessing. So, considering that, are you confident enough to achieve what we have been trying to fetch from the complex portfolio going ahead?

Vinita Gupta: We've already started seeing the benefit of the complex products, just a couple of products like Albuterol, what -- how much they benefit from us, from a profitability standpoint. We can't wait for our portfolio to be rolled out completely. I mean, when Spiriva gets approved, the potential of Spiriva is substantial, both on top line and as well as bottom line. And we will execute on these opportunities. Meanwhile, until they get delayed, one feels uncertain about them, but the fact is, our team is working one hundred percent to get these products approved and launched. And as we look at launching these products that will really help us grow the top line as well as the margin profile, we feel confident of getting to that in the next couple of years to 17% to 18% EBITDA level.

Surya Patra: Okay. But whether you are happy to achieve whatever the profitability that you have achieved in case of Albuterol, ma'am? Because that is a concern that, okay, that was a key product and we have been targeting certain level of market share and we achieved everything. But that has not influenced anything at all to our overall profitability. Although, there has been incremental competition, incremental challenges that was -- generally that has come up, but still. So, given the scenario whether we should see whether the kind of profitability that we are trying to achieve, will that justify the kind of money that we have been spending on the complex portfolio?

Vinita Gupta: I would say that actually, Albuterol offset a lot of challenges of the oral solid portfolio and the erosion that we saw on the oral solid portfolio. And as we look out the next two years, we are expecting that Albuterol will have some price pressure / price erosion and that we are factoring in new products that we bring in to the market that will help us bolster the top line and bottom line.

Surya Patra: Okay. My second question is on Spiriva. See, obviously it is delayed a bit. But in the meanwhile, have you understood anything about the potential competition in that product and why and when?

Vinita Gupta: Yeah. So, we don't believe, I mean, as of yet no one has really finished clinical trial. We believe that one company has started working on the trial. They are just starting a PD study. So, from anyone who's starting a PD study right now, if I look at our timeline, they are going to be three years away at least to get the product to the market.

Surya Patra: Okay. So till the time that we will be having kind of exclusivity situation in Spiriva, whether that will have some kind of advantage in terms of grabbing market share for other products -- other respiratory product as well or there is no contentious benefit that we should see?

Vinita Gupta: Well, I wouldn't mean that would be an upside. If we can get it, I mean, we are strengthening our respiratory portfolio. So overall our position on the respiratory and our offering from a customer standpoint goes up, but that will really be an upside to see how we can bundle them if we can at all. I mean, to us it's just a standalone, a very lucrative opportunity.

Surya Patra: Sure. Just last one question about the numbers basically. So, whether any debt number that has been added during the quarter, because the finance cost looks slightly elevated this quarter? That is one. And could you also clear what was the flu contribution this quarter just, means the sequential up move in the US sales what we have witnessed? How much was that driven by flu?

Ramesh Swaminathan: Firstly, on the debt front, yes. So, we had a couple of acquisitions, the brands that we bought in America, we also bought brands in Brazil. That's actually come on to the scene. And there is of course the normal capital expenditure that we continue, which would have come through in previous quarters also. So these have actually in some ways taken up the overall debt position. Though there has been a reduction on the working capital front, this is -- it's the M&A front, which has cost us for -- to take on some debt.

Surya Patra: What is the gross debt, sir?

Ramesh Swaminathan: It comes to about total about INR3,400 crores is net debt and about INR4,600 crores is gross debt.

Surya Patra: Okay. Thank you, sir. And anything Flu season contribution for the quarter, ma'am?

Vinita Gupta: So, its A low single digit, couple of million dollars.

Surya Patra: Sure. Yeah. Thank you, ma'am.

Ramesh Swaminathan: PenG prices have been ruling at a particular and at a higher end, because of that, to that extent, that ability to kind of -- we didn't actually want to sell at a

loss in America also because prices are what they are. We have been focusing on only products that are profitable.

Moderator: Thank you very much. The next question is from Neha Manpuria.

Neha Manpuria: Yeah, thanks for taking my question. Nilesh, my first question is on the India business. I think you mentioned we should get back to double-digit growth from second quarter onwards. So, at that point, most of the Cidmus impact and also the diabetes impact will be behind us. And we expect the MR to start contributing to productivity. That assumption is right; we should start seeing outperformance versus industry from second quarter.

Nilesh Gupta: Yes. And I actually we did not even talk about the NLEM impact that we are seeing little bit in the end of Q3 and then we'll obviously have that in Q4 and then obviously a good portion of that we would expect to reverse in Q1.

Neha Manpuria: Understood. And if I were to look at the business in a little more two to three-year perspective, do you think we need any investments, organic and inorganic to sort of bolster our position further in India?

Nilesh Gupta: I think we are doubling down on India, adding a 1,000 representatives. We are cognizant of what that means in terms of employee expense, in terms of selling promotion and the like. But we see this as an opportunity to grow in India. Obviously, in the COVID period, we held back from adding people and the like. And again what we're doing is no different from the other industry leaders where clearly there is a renewed focus on India. And it certainly is part of our plan as well. I think we are already committed to doing whatever is required from a people perspective and expense perspective and R&D perspective to get growth to the business.

I would love to hold in inorganic moves in this as well. We did some smaller stuff including buying the in-licensed product Ondero and the Anglo-French portfolio, which is actually performing very well. But I think acquisitions are going to be few and far between, because especially the somewhat bigger ones as you've seen, it gets to a multiple that you really can't justify. So we would seek value and that would make it difficult from an inorganic perspective, but we are looking at everything that comes our way and for our own part digging out opportunities that we could chase as well.

Neha Manpuria: Understood. Given that we are doubling down on India and most of the competition is increasing field force, SG&A. How do I put that in context with the fact that we want to look at cost optimization further? That would indicate that our costs are probably -optimization whatever might come through might be more than offset by the fact that we need to continue to invest to grow in India, which does makes margin expansion without Spiriva nearly impossible. Is that the right conclusion?

Nilesh Gupta: So maybe I can start. Ramesh, you can add. I think, first of all, there are some period effects. Yes, we are adding people. Yes, there will be certain costs

associated with that and we will not get a return obviously the very day that we add those people. I think the cost optimization measures are largely driven from the optimization that we saw overall from a generic footprint perspective. So, lot of the stuff that we've done, optimizing the R&D spend, optimizing the manpower footprint: 16% reduction in our workforce, in our manufacturing plants, optimizing the R&D work force and the like, a lot of that is gone in the direction that the generic market is changing. We will obviously play in oral solids and the like, as well. But clearly, the focus is to be a specialized generic player focusing on inhalation, injectables, and select oral solids.

So I think that -- to me those optimizations run in parallel. There are still obviously five or six key growth drivers and big business areas within Lupin. And some of them will take investments at certain point of time, the others will get optimized. But net-net, obviously we're all working to build a high growth organization with growth at strong double-digit and obviously with EBITDA far better than what we have right now. We are very cognizant of the fact that we are under indexed. So I think these investments are being made in light of everything else that is happening, but obviously with the view that in the next few quarters, we should be getting to much more solid numbers.

Ramesh Swaminathan: Neha, just to add to that and give further colour, there is a base beyond which it is impossible to go on quite a few buckets. And to that extent, perhaps there's some buckets which is not possible to kind of optimize further. But I also identified a few buckets where a great deal of optimization is still possible. This is essentially in terms of the footprint reduction in some ways. Potentially you could also look at the idle time associated with that. And third bucket potentially be on the reduction -- on the inventory write-offs that we have seen so far. So those buckets will certainly contribute in some base to further efficiencies. And that will certainly move the needle.

And you are also speaking the same breadth of in fact of two-to-three-year horizon. And when we get to that point, we are talking about quite a few products coming through. Spiriva certainly, in our opinion, should certainly come through with great deal of confidence we're saying this, in the first half of the current year itself. And then we are also lining up in fact for products for the future. We are working on in fact the injectables portfolio. We are working on the entire respiratory range. And there is every conceivable product which is worthwhile looking at, we're looking at out there. And we are pivoting a lot more towards complex ones. So, to that extent, there's a lot more stickiness associated with that, realizations associated with that, which is perhaps not that you will see in the OSD portfolio at least in recent times. So I think, whilst, there is further optimization possible on the cost front, a lot more possibilities for the top line. And that as you know -- and EBITDA is ultimately going to be the difference between the two. And of course, R&D expense, to our mind, whilst we pivot to in fact the more complex ones, as a percentage of sales, it'll certainly keep going down only. So I differ with you and I would say that EBITDA

margins in the next two to three years will certainly be much higher than what is today. Clearly, it's an absolute nadir from my perspective and 18% to 20% over the next two to three years is -- from my perspective is a certainty.

Neha Manpuria: Understood. And last question, if I may. Vinita, you mentioned about the Nagpur facility clearance helping unfold on injectable pipeline. Could you give us some colour on the number of launches or the opportunity size that we're looking in injectables next year or the year after? Any colour would be helpful.

Vinita Gupta: Yeah. So now that we've got the approval, I mean, we are also accelerating our portfolio, looking at some of the contract manufactured products that we can bring in-house where we haven't had the right cost and supply position. I think in the fiscal year '24; we potentially can bring four to five products into the market. We have couple of filings that are pending. Glucagon, Bumetanide, famotidine as well as all the products that we are -we manufacture outside that we can bringing in-house in Nagpur with the right cost structure. So, four to five products in the next fiscal year. We'll try to accelerate that and a larger number in the year after.

Neha Manpuria: Thank you, Vinita.

Moderator: The next question is from Niteen Dharmawat.

Niteen Dharmawat: I see that we are continuously changing our strategy. So, I see that wherever there is a momentum, we go over there. We started somewhere in pathology, now we are hiring 1,000 people for India business. Earlier it was Japan. We made acquisitions in USA. And things are not working and that's why we are making too many changes. Is that the case? Are we making too many changes with our strategy?

Vinita Gupta: Actually, we are not making any changes on our strategy. I mean, we've been very focused on building our core business which is: one, India; two, our US complex generic business; three, anywhere we can get operating leverage like other developed markets with our generic portfolio, the investment that we've made in our pipeline and in our manufacturing facilities; and four, the other emerging markets, which pretty much are self sufficient in terms of their P&L as well as the cash flow requirements. So, there's no real change in -- I mean, the only change in strategy that has happened over the last couple of years, I'd say is a sharper focus on complex generics, more specialist in portfolio versus a broad generic portfolio.

Ramesh Swaminathan: And the entry into Japan 12 years ago and the exit were very well crafted strategy, so to speak. There was nothing tactical about it at all. So, our entry into in fact complex generics, injectables, biosimilars, inhalation space are all very well crafted and to that extent, we've been very consistent in actually going down the path as far as spends on those. There has been no change whatsoever.

Niteen Dharmawat: I understand. So, can you give some guidance for the current financial year and the next financial year for top line as well as for EBITDA margins?

Ramesh Swaminathan: EBITDA margin, if we talk about the next quarter, potentially, it will be around the same lines as the current quarter. But I've also indicated that things will get progressively better because we're working on several things on the cost front. And on the top line front, we keep reiterating the fact that there would be products coming in. So, things will only get better.

Niteen Dharmawat: I see. And for the next financial year.

Ramesh Swaminathan: Our ideal target would be to get to the core of 20% that the competition is currently at. Whether we get there in the fourth quarter of next year or in FY24-25 -- the overall direction is there. The target is that. And there's no reason why we should not get there, because all the initiatives are in place, and we are going down the path of our strategy without retracing any of those.

Nilesh Gupta: The top line also we're looking at double-digit growth.

Ramesh Swaminathan: Yes. Across the markets really.

Moderator: Thank you very much. The next question is from Sameer Baisiwala.

Sameer Baisiwala: Hi, good evening, everyone. Vinita, if I'm not wrong, FDA had already inspected the site for Spiriva, isn't it? So, why should there be a need to do it again?

Vinita Gupta: No, they have, and I don't know if there is a need to do it again, Sameer. It all depends on the agency though.

Nilesh Gupta: Standard language, I think.

Vinita Gupta: Yeah, it's been inspected before.

Sameer Baisiwala: Okay. But they have given you two dates, so that means they are thinking about it. Yeah.

Vinita Gupta: We don't know. So, they always give you two dates and its very standard language from the agency now on any product. So that's why we can't say for certain that it's going be April only.

Sameer Baisiwala: Okay. Got it. And, Vinita, what transpired in November TAD date? In the sense, I thought that there was a good chance that they might have approved then itself, so...

Vinita Gupta: No, so we got our priority review in November when we had reported. And at that point in time, we got -- we were expecting an approval close to an eligible launch stage, which should be very close to April actually.

Sameer Baisiwala: Okay. Got it. And the second question, Vinita, are you seeing the competitive intensity in the US for OSD is going up or is it much the same for the three, four products that you mentioned that you saw some price erosion. Were there

new entrants which were bidding lower or even without new entrants, you are seeing prices roll down?

Vinita Gupta: Actually, we have seen some rationalization on -- and a little bit of reprieve on the price erosion front because there's been a lot of erosion and companies have started to get out of products that we have gotten out of the couple of products, which really worry our customers. So there has been also supply disruptions with a lot of challenges that companies have had and some are due to the margin pressure, but otherwise GMP related issues. So, we are seeing a degree of getting back to high single digit price erosion at this point. And we'll see that continue in this calendar year.

Sameer Baisiwala: So, Vinita, if I may ask, how profitable is our US business as it stands today? If you can just talk about it, because is that what is taking the entire company average way below and how sustainable is it to do business in this manner for a company which is probably the lowest cost producer in that sense?

Vinita Gupta: Yeah, I'd say that the US business EBITDA is below the company EBITDA right now, but I can tell you that when we look at the last full year, I mean, Q3 was probably the quarter where the US business did the best from an EBITDA perspective. So given all the efforts on the cost optimization front, R&D optimization, stabilizing the base as well as executing on the new product launches, we have been able to get Q3 to a much better level than it was in Q2 and Q1. And we continue to build upon it. And two years ago, the US generic business was above the company average EBITDA. And, subject to Spiriva happening and some of the other product launches, which are certain, like Darunavir is certain and the like, we expect the US EBITDA again from fiscal year '24 to be above the company's average level of EBITDA. Otherwise, we'll continue to optimize it.

Sameer Baisiwala: Okay, that's great.

Ramesh Swaminathan: You recognize, Sameer, as well as I do, it was a feast for quite some time. There has been a bit of a famine out there in the last two to three years. But it's not as though this party will never begin again. It will -- so once we get the products in place, things should be much better.

Sameer Baisiwala: Yeah, sure. Ramesh, my worry is, excluding Albuterol, is it a bit in the red kind of a business and it's not about Lupin is just about -- is this a sustainable business model in general for generics to be supplying at the pricing that it is, given the consolidated buying in the US?

Ramesh Swaminathan: And you also know this, so the entire business is kind of pivoting away from OSD into more complex ones. And these are more commoditized products is where there is intensity -- there is so much of competition. And one doesn't really make too much of moneys out there. So -- and to the extent, company should have focused on moving out of OSD and this is exactly what we're trying to do also.

Sameer Baisiwala: Okay, great. One final question from my side, if I may. It's on Suprep. Vinita, two parts. One is, how has the pricing been, typical exclusivity type pricing 40% erosion or -- and second post 180 days, how do you see the competition coming up?

Vinita Gupta: Yeah. So, it has been a two-player market, the authorized generic, the brand launched in authorized generic and us. It's been a very, very nice opportunity from a margin perspective. Price erosion even in a two-player market is 60% or so. So there has been that kind of price erosion. However, the run rate that we see is looking better beyond the 180 days, because we believe that the other players have supply issues on the API. That really is impacting the product approval and launch.

Sameer Baisiwala: Okay, great. Thank you so much.

Vinita Gupta: Thank you.

Moderator: Thank you very much. The next question is from Bino Pathiparampil.

Bino Pathiparampil: Hi, good afternoon and good morning. Vinita, just a couple of specific questions on products. Darunavir, you just mentioned. So, we are set for launch of 600 and 800 in 1Q, right?

Vinita Gupta: That's right.

Bino Pathiparampil: Okay. And are we going to follow that up with the other strengths after six months or so?

Vinita Gupta: I believe so. I mean, the material opportunity, the larger opportunity we see is the exclusive strength that we have in the majority of our revenues that we see. The upside is for the exclusive strength.

Bino Pathiparampil: Got it. And what's the update on pegfilgrastim in the US, I believe you are looking forward to approval near term?

Vinita Gupta: Yeah. So, we responded to the agency on the queries that they had, just in the last couple of weeks and we believe that we've been able to satisfy, from our perspective, all of the questions that they have. So fingers crossed that we get that approval in the next couple of months.

Bino Pathiparampil: Next couple of months. Okay. Understood. And any further update on Dulera? I believe there also you had some queries to which you responded.

Vinita Gupta: Yeah. So on Dulera, we have received a CRL from the agency and we need to do some additional work on the product that is ongoing. So we'll have to respond to the CRL which we haven't responded as of yet.

Bino Pathiparampil: Understood. Yeah. Perfect. Thank you very much.

Moderator: Thank you. The next question is from Shyam Srinivasan.

Shyam Srinivasan: Good evening and thank you for taking my question. Just the first one is a data point on the India business. What's the current field force, like you talked about 1,000 people, but where were we at say March end and now, so what's the absolute number?

Nilesh Gupta: At end of this, we will be at 7,100 reps and 9,300 as the total sales force.

Shyam Srinivasan: Got it. Thanks, Nilesh. So, when we track the progress and you've guided to quarter two next year where you'll start growing faster than the market, so what are some of the monitorables, maybe PCPM, if you could -- doctor coverage, if you could guide us to some of the things that we need to be watching out for?

Nilesh Gupta: I think we should just be watching out for the total number where we report. I think there's too much granularity. Our PCPM is actually pretty good. Our overall PCPM is an 8.6 lakhs per representative. So it's actually a pretty good number overall, but there is a spread. I mean, in an acute business, it's going to be lower, it's higher in more chronic high end business. So, I wouldn't try to watch out for those things. The divisions that we are adding are in the big areas. So there is -- there are -- there is the metabolic division, there is another respiratory division. So, but I think one of it will reflect in the total numbers and the therapy-wise numbers.

Shyam Srinivasan: Got it. Nilesh, helpful. My second question is just on regulatory compliance and just maybe you can -- Nilesh can answer it from an industry perspective as well, right. So, when participants ask what is the contribution from Mandideep, why is that question being asked? Is it because people worry that every OAI is now equivalent to an import alert? So just which is surprising. So, after so many years of having to work with the FDA, so how should we think about the dynamic and what are you hearing when you interact with inspectors, quality people? What are some of the feedbacks that you're picking up?

Nilesh Gupta: I appreciate you asking this question. From the industry perspective, I think there is an over-heightened sensitivity to every 483 that there is. But obviously if there are excessive number of 483s or obviously other regulatory action, that is of concern. There's no question about that. And from an industry perspective, we've obviously had a few examples where quality is somewhat pretty bad in other markets and the like. And unfortunately, I think that brings the industry in a bad light. We are coming out from -- we had I believe about 60 odd inspections in India in 2022 versus the normal 200 plus. So obviously we're getting into a period where there will be more FDA inspections and with the number of facilities that we have, as an industry, there will be obviously some portion of negative outcome that will come out as well. But I think - I would only -- we had five observations in Nagpur. Everybody gave us a hard time. We've got the approval thereafter, right. So, I think the nature of the observations is important and not just not just the numbers. So I think it's important to get a little bit deeper into this which is I think you guys do a great job of that.

Nilesh Gupta: As far as we're concerned, I think we've had some wins and some misses. Ankleshwar was a win. Nagpur was a win. Somerset was a very nice win. Even with the follow-on inspection, Mandideep clearly, we were not at the right level. We're taking the right steps to not blow out further than what it is. But it's not acceptable. Tarapur is not acceptable as well. And there is a clear remediation plan on this. So, we do believe that we will get them to the right spot. We're not just going to leave them there just because the contribution maybe below a certain level. Whatever we supply, every product that we supply has to be of the right quality. People don't have to look at where the product was made. So, we are committed to this. I think the industry is committed to it in a broader sense as well. Certainly, it is scrutiny on industry is going to be there. And we have to be up to snuff.

Shyam Srinivasan: Thank you. Thank you so much. Thank you.

Moderator: Sure. The next question is from Madhav M.

Madhav Marda: Yeah. My only question was the -- you said that the R&D expense as a percent of sales should come down as the revenue base goes up. Could you give us a sense? I think we should be about 8% or so for this year, but what is the FY24-25 look like as a percent of sales, if you could give us some sense?

Ramesh Swaminathan: Yeah. So, this year is going to be about 8%, but in the subsequent years, it will certainly come down by 1 percentage or 2 percentage for sure.

Madhav Marda: 1 percentage or 2 percentage? So, could be in the 6% to 7%?

Ramesh Swaminathan: 1 percentage to 2 percentage points lower I would say over time.

Madhav Marda: Got it. Okay, perfect. Thank you, Ramesh.

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

Vinita Gupta: Hopefully, we've been able to answer all your questions. We hear all your concerns on the margin front. It was not too long ago, couple of quarters ago that we were in a single digit margin. And the fact that we've been able to pull the business back up to double-digit in Q2 and then further improve it in Q3, we will continue to work on this front to ensure that we continue to grow our business in a profitable manner. We certainly don't feel we're anywhere close to our potential as an organization, but we're moving in the right direction, and we will ensure that we can get to our true potential. It might take us couple of quarters longer just given the delays in product approvals, but we will get there. Thank you.

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