“Lupin Limited Q2 FY2023 Earnings Conference Call”

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MANAGEMENT:

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- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
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Moderator: Welcome to Lupin Limited Q2 FY23 Earnings Conference Call. Please note that all participants' line will be in the 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, sir.

Vinita Gupta: Hi, everyone. This is Vinita Gupta here. A very warm welcome to our Q2 earnings call. I have with me our Managing Director, Nilesh, as well as our CFO, Ramesh and members of our Finance and Investor Relations teams. Trust you all have seen our numbers for the quarter, and Ramesh will share a deeper analysis of our performance.

As you would have noted, our business has improved. Revenue growth was driven by the bounce back of our U.S. business along with continued growth in our India business, and also growth across all other geographies. On the margin front, we see the benefit of our optimization measures in addition to the revenue growth in the business. We are focused on sustaining this positive momentum for the rest of the year.

I would like to share some of the business highlights with you. On the U.S. front, 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 respiratory franchise contribution increased, and we executed on a couple of new product launches in particular Suprep that will help growth in Q3 and Q4. It had some contribution in Q2, but since it was launched in September, more to come in Q3 and Q4.

In addition, we closed our acquisition of the Sunovion brands, Brovana and Xopenex that will enable us to enhance our respiratory position in the U.S., while contributing to revenue as well as profitability growth. As we look at the quarters ahead, we have new product launches like Spiriva, Diazepam Gel, Nascobal Nasal Spray and Darunavir, multiple products where we have exclusivity or first-to-market position that will enable us to grow our U.S. business in a profitable manner.

On Spiriva, while we had hoped to get an approval by now, we are close. We have responded to all the queries the agency had raised and are working closely with the FDA to get approval by our eligible launch date. We will know more in the next few weeks, and we'll share what we learn with all of you. In any case, we see this as a substantial contributor for fiscal year '24 and will definitely have a significant runway based on the competitive position at present.

Switching to India, the largest part of our business, while our growth in the quarter and the first half has been below market, this is primarily due to the loss of Cidmus from our cardiovascular portfolio and generalisation in the gliptins. But for the diabetes portfolio, our India business grew ahead of the market. Also, the diabetes franchise, while impacted in the near term, we expect growth in the mid- to long term given the continued growth in diagnosis and increased affordability with generics coming to the market, and our own generics.

In our top therapy areas, respiratory and cardiac growth was in line with the market and therapeutic areas that we are trying to build like GI and women's health were well above the market. We expect the second half of the year to be better than H1 from a growth perspective and are committed to get our India business back to double-digit growth in the quarters and years to come.

All other markets continued to grow and perform as per expectations, in particular, we saw a really strong local currency growth in Mexico and strong double-digit growth across Australia, Germany, Canada and U.K., our other developed markets.

On the margin front, we have seen significant efforts that we have had underway in the last 12 to 18 months' payoff, our margins did improve, and we expect to see this benefit continue in the quarters to come despite inflationary pressures. A word on the compliance front, we have made progress this past year with the clearance of Goa and Somerset warning letters and successful inspection of Ankleshwar and Nagpur. However, the warning letter at Tarapur certainly was disappointing for us. We have clarified with the agency that it is only specific products that we have discontinued over the last couple of years from the site and we continue to manufacture a number of key products with a clear commitment to meet the FDA's concerns on nitrosamine and cross-contamination that they highlighted to us during the inspection and in the warning letter.

Overall, we are moving in the right direction, as you can see from what we have delivered in the quarter and are really committed to grow both revenues and profitability in the quarters to come, while executing on our strategic plan.

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

Ramesh Swaminathan: Thank you, Vinita. Sales for Q2 FY '23 are INR 4,091 crores as compared to INR 3,604 crores in the previous quarter, a growth of about 13.5% quarter-on-quarter. Year-on year basis, it was about 2.2% as compared to Q2 FY '22 sales of INR 4,003 crores. I would just go on to the margins a bit. FY '23 Q2 gross margin was 58.1% as compared to Q1 of 55.3%. This is mainly due to one-time shelf stock adjustment in the previous quarter, and in this quarter, we also

had optimization of freight costs, both mix and rate and other write-offs and better product mix as well.

There was, of course, some price erosion, which was well contained though. On the employee benefit bit, Q2 FY '23 is INR 771 crores vis-a-vis INR 778 crores in the previous quarter. Manufacturing expenses, very well contained again, FY '23 was INR 1,226 crores vis-a-vis INR 1,191 crores in line with the sales development itself. EBITDA, operating EBITDA, excluding FX and other income, is 10.6% in Q2 FY '23. Quarter-on-quarter growth in EBITDA is about 610 basis points, which is led by expansion of gross margins over Q1 and higher sales growth, which is again reported across various regions. R&D is flat as compared to Q2 FY '22 at 8.3%.

ETR, normalized ETR is expected to be between 31% and 34% as few subsidiaries like LI, LOI, Digital and Healthcare continue to make losses. Operating working capital days improved to about 140 days in Q2, visa-vis 147 days in Q1 of FY '23, a reduction in inventory despite delivering higher sales.

And with this, may I open the floor for discussions.

Moderator: Thank you very much. We will now begin the question-and-answer session. First question is from Neha.

Neha Manpuria: Ramesh, on the operating cost in the quarter, last quarter we had indicated a fair bit of cost optimization efforts that you know we were expecting. Well you've seen gross margin improvement or operating cost, especially employee cost, other expenses, hasn't seen the reduction, we had also indicated closure of facility. So, could you put some give us some color there please?

Ramesh Swaminathan: Yes. Sure, Neha. There are several initiatives that we have been carrying on, and also we have been focusing on gross margins apart from what we are doing on the top line front itself and as we looked on alternate vendor development in terms of routes to synthesis etcetera for the gross margins bit.

In terms of the manpower itself, yes, we did go through, in fact, with the workforce planning at the factory level. There was a reduction, and you'll find a lot more coming up in Q3 and Q4 as well. I think there is a shift between lines, essentially that's the reason why you're actually found it to be a little flattish when it comes to the manpower lines itself, but believe me that there has been overall reduction, which has come through.

On the SG&A front, there is a lot more of sales promotion in line with the overall sales development itself, and that's across various regions, including India. But despite all of that, you would see that the overall margins have

actually gone up, and so that's in line with the development of the gross margins front as well as the evolution on the sales front.

Neha Manpuria: Are we sticking to the guidance that we gave last quarter of exit margins?

Ramesh Swaminathan: It really depends on the product top line profile really. So if we do get the kind of products that we were anticipating, then you would look at an exit rate, which is more in line with our overall anticipation for the future.

Neha Manpuria: Okay, which would be the number that we had mentioned before in the last quarter?

Ramesh Swaminathan: Yes, around that.

Neha Manpuria: Okay, Got it. Vinita, on the U.S. business, given we had a lot of one-off and moving parts in the last quarter, if I were to look at the base business, how has the pricing erosion been in the base? And have we been able to regain some of the lost share in the existing products or was all of the improvement driven by new launches?

Vinita Gupta: No, so Neha, part of the improvement was just the fact that we had the one-time correction, right, in Q1 so, and we had a normalized quarter in Q2. In our in line products, the bulk of the oral solid portfolio, we had a reasonable price erosion, not double digit, so definitely price erosion was more measured.

On the respiratory franchise, actually we have seen a good improvement. It's become a larger part of our business, so that contributed nicely to revenue growth as well as profitability growth. And the new product launches, we had 3, and Suprep was material, but also Suprep was in the last, the end of the quarter in September, so we got a little bit of contribution in Q2, we'll have more to come in Q3 and Q4. So, majority of the revenue growth was the existing portfolio, both oral solids as well as respiratory.

Neha Manpuria: Got it. And last question if I may, we added the 2 brands that we've acquired in the current quarter. Given we already have generic, the thought process of acquiring these brands?

Vinita Gupta: Yes, so one, it enhances our respiratory portfolio. We have added Xopenex as a product in our respiratory offering, which certainly enhances our position in the respiratory front. On the Brovana front, we were already a partner, authorized generic partner, and we had a percentage, so we obviously have synergies there and have the end-to-end P&L on the Brovana front, which is attractive to us. So, we will continue to maximize the 2 products and look at ways and means of, one, stabilizing the revenues of Xopenex and potentially building synergies on both products given our manufacturing capability across both MDIs as well as refills.

Moderator: The next question is from Saion Mukherjee.

Saion Mukherjee: This is Saion from Nomura. Vinita, just to carry on Xopenex and Brovana, can you share the size that you're looking at for these 2 products? And you mentioned about stabilizing sales, so what is the dynamics on Xopenex here? And on Brovana, I understand brands still has around 13%, 14% market share, so is that what you'd be continuing selling? So, if you can give just some indication on the size? And also, the $75 million, how would you sort of amortize it? What's the time frame for that? .

Vinita Gupta: I'm just taking that $75 million first, I mean the franchise is accretive in year 1. So we were very pleased to be able to transact at the level that we closed. I can't share product-specific details because as you know Brovana is part of our generic portfolio, the authorized generic is part of our generic portfolio. I mean, you can look at the IMS dollars of both products as well as the authorized generic, so it's substantial from IMS dollars.

But needless to say, the products have been accretive, will be accretive in the current fiscal year and provide synergies both in Brovana as well as obviously, incremental revenues and profitability of the residual brand. It gives us a residual brand revenue line and potential synergies on our cost of goods going forward?

Saion Mukherjee: And when you say accretive, you are meaning EPS accretive, and that's why I was asking how we amortize the $75 million.

Vinita Gupta: Yes, EPS accretive.

Saion Mukherjee: And you should be amortizing it over what period, the $75 million?

Ramesh Swaminathan: So, insofar as Brovana is concerned, it's going to be a much lower period. For that it's going to be more in terms of what we think is an appropriate period, but the accounting rules doesn't provide for anything more than 10 years, so it's going to be shorter than that?

Vinita Gupta: It's much shorter than that too. Yes.

Saion Mukherjee: Okay. And Vinita can you share like which one is a bigger franchise now, Xopenex or Brovana. I mean, I know you can't share the exact revenue number? And in terms of dynamics, do you expect competition in Xopenex at some point or you expect it to be sort of a stable brand?

Vinita Gupta: Yes, we expect it to be a stable brand. Between the 2 products, they are kind of equal, right now in terms of revenue, but Brovana obviously has got multiple generic competitors. So, we expect it to come down, while still having some residual revenues in the brand. While Xopenex we see as a stable opportunity in the foreseeable future just given the scale of the product, the

size of the product and the fact that one would have to do a clinical study to be able to get a generic version approved and the like.

Moderator: The next question is from Prakash Agarwal.

Prakash Agarwal: Hello, am I audible?

Ramesh Swaminathan: Yes.

Prakash Agarwal: Just a quick update on Spiriva, where are we? Last time you said you had query on the products, so what is the timeframe, and have we replied and when are we expecting?

Vinita Gupta: Yes, Prakash, so we have responded to the queries fully within October, and have filed also for priority review, which we are working with the agency. We'll know in the next couple of weeks the status of our request, but are working closely with the agency to get approval on eligible launch date later this fiscal year?

Prakash Agarwal: Okay. And eligible launch date is in Q3 or Q4, it was Q3, right?

Vinita Gupta: No, it was the second half, end of second half?

Prakash Agarwal: Okay. And just was checking, I mean how is the flu season, has it started, hearing that it can be a flu season this year, so are we hopeful of the Tamiflu we had in the past or that is now much genericized?

Vinita Gupta: No, so the first time after a couple of years, we are seeing some impact of the flu season, so we've seen an uptick in anti-infectives as well as Tamiflu, a little bit in Q2, but we're expecting a strong flu season, if all of the predictions in the U.S. I mean, they're talking about a strong flu season, COVID as well as RSV, a combination of multiple issues. We're also seeing the flu season impact on our purchase orders on the API front, on the cephalosporins. So, both the U.S. indicators as well as API forecast suggests that the flu season right now seems to be picking up.

Prakash Agarwal: Okay. Perfect. And lastly, you made the acquisition of these 2 brands. Going forward, I mean, it was just opportunistic or that could be a strategy going forward and that too specifically in respiratory or it could be any therapy?

Vinita Gupta: Yes, so it wasn't opportunistic, it was actually strategic. We had told our team that we want to grow our respiratory franchise with established brands. We didn't have multiple opportunities on new pipeline programs, but didn't want to get into dilutive assets. So we had looked at multiple opportunities, and really focused on this one to look at what we can do from a synergy perspective. Certainly, had synergies on Brovana, but as we looked at Xopenex as well, we really liked the product, we liked the product profile. It hasn't been promoted in multiple years, so we will evaluate the potential of

promoting the product with a small-scale investment, and also look at leveraging our manufacturing capability to improve the margin profile of the product. Right now, it's contract manufactured, and we'll certainly continue the relationships in the next couple of years. But as we look at maximizing value from the opportunity, we'll look at also bringing in synergies from a manufacturing capability.

Prakash Agarwal: Okay. And lastly on the margin outlook, the margin outlook was around 15%, 16%, correct me if I'm wrong, and this is without the Spiriva opportunity exit rate of Q4?

Ramesh Swaminathan: No. I would say that it really is a function of the kind of products that we bring. So if we have Spiriva coming in fourth quarter, it will certainly have its bearing on the margin there. So the guidance that I spoke about was essentially based again on Spiriva coming in.

Vinita Gupta: Yes. I think it's fair to say that you will see continued improvement on margin quarter after quarter.

Ramesh Swaminathan: That's true.

Vinita Gupta: But really to get to that 16% level plus, which we are working towards, we need material launches like Spiriva. And we have a good few products coming with Spiriva hopefully in Q4, and soon after that products like Darunavir, where we have exclusivity, plus Nascobal Nasal Spray a little bit later in Q1 next year, Diazepam Gel.

So we have a couple of new product approvals that we are chasing, hopefully in the next couple of months we'll have a better idea of the launch timelines of each. There is a very strong focus on trying to bring them to market at present. But as we launch these material products and particular products like Spiriva and Darunavir, we expect the margins to improve to that 16% plus level.

Prakash Agarwal: Okay. Thank you. And all the best.

Moderator: Thank you. The next question is from Kunal.

Kunal: Thank you for taking my question. So I think at some point, we were expecting plant inspection related to Spiriva approval, is it still the case or we still don't have clarity on that?

Vinita D. Gupta: We actually had record review, plant record review. We have also gone through an assessment on PK and PD satisfactorily. So we believe that we have given the agency everything that they've asked for. But again, it's their

prerogative to come and inspect if they wanted to. We'll find out in the next couple of weeks where our priority review request stands, and that will give us a good idea, if there will be any plant inspection.

Kunal: Do we have any TAD date as of now?

Vinita Gupta: Like I said we just filed for a priority review, and we'll have a TAD date in November for the request, in the next couple of weeks.

Kunal: So you will get TAD date in November, you have TAD?

Vinita Gupta: Yes.

Kunal: Okay. And the second question on the acquisition, I think our press release mentioned that we'll also have whatever infrastructure is required for this product. Does it include any kind of manufacturing line or something?

Vinita Gupta: No, it's just an asset acquisition. No manufacturing, we have the manufacturing capability.

Kunal: So currently it is manufactured by someone else, you would bring it to our own plant, is it?

Vinita Gupta: Over time, some Brovana sooner than Xopenex, but we have opportunity, the potential to bring it back in-house.

Kunal: Okay. And let's say, one last question on the cost initiative, I think we were very sure that there will be INR 20 crores savings in the employee cost line item in quarter 2. So what has changed? Why it has not materialized, or it has materialized and there is some cost inflation that is coming in the quarter 2?

Ramesh Swaminathan: It has certainly very well materialized. There is, of course, our savings there. But there has been a shift between lines. It shifted from impact on parallel lines for certain incentives etcetera to the salesman, which is coming to the sales figure, to the salaries, employee figure.

Vinita D. Gupta: Employee figure so for India.

Ramesh Swaminathan: Yes, in India.

Vinita Gupta: So there have been savings on the workforce planning that we did in the last quarter, but offset by additional

Ramesh Swaminathan: Shift in lines.

Vinita Gupta: Yes.

Kunal: Okay. And if I may ask just a last one, in terms of the FT, failure to supply penalty, what would be that number for this quarter?

Vinita Gupta: It was marginal actually. It's come down significantly. Actually, there was a good amount of savings both in failure to supply penalties as well as freight cost as Ramesh mentioned as well.

Kunal: Okay. So, last quarter it was $4 million and this quarter is almost 0?

Vinita D. Gupta: It's under $2 million.

Ramesh Swaminathan: Yes, it's marginal actually.

Moderator: Thank you. The next question is from Vinay.

Bino Pathiparampil: Am I audible? Hello?

Moderator: Yes.

Bino Pathiparampil: Congrats on a great improvement and thanks for taking my question. Vinita, just a couple of clarifications, for Darunavir, did you say Q1 FY '24?

Vinita Gupta: That's right.

Bino Pathiparampil: Okay. Just a couple of other product queries, any update on Dulera filing?

Vinita Gupta: Yes, Dulera we had a CRL that we responded to the agency very recently.

Bino Pathiparampil: Okay. So, do you expect to hear anything in the next 6 or 12 months?

Vinita Gupta: Yes, we expect in the next couple of months to find out if the agency is satisfied with our response or we need to do more work on the product.

Bino Pathiparampil: Okay. And so, where does this product generally move, in which you will have a final approval, any timelines for the launch?

Vinita Gupta: I don't know exactly when the launch stage is for that product. The near-term products as I mentioned are Spiriva, Darunavir, Diazepam and Nascobal, where we have exclusivity as well. But beyond that, products like Varenicline, will be material next year as well. And then injectable products, based on our inspection of our biotech plant, we would expect pegfilgrastim approval based on the inspection of our Nagpur facility recently. We expect products like glucagon to be approved and the like.

Bino Pathiparampil: Understood. Great. My final question to Ramesh, the tax rate is running around 31% to 34%, which is much higher than the corporate tax rates in

India. So how do you see this panning out over the next couple of years, and do you have a plan in place to bring it down?

Ramesh Swaminathan: Yes, so, whilst, if you look at, in fact, standalone results, the absolute numbers in India and the percentage would be lower. It's only the presence of in fact some loss making subsidiaries in various parts that is actually causing this number to deteriorate. And the first quarter, of course, there was this anomaly, because of lower sales in America caused because of the stock situation being what a buzz.

But we are very much conscious of this and for the full year actually you would see it going down for the year end, and the fourth quarter, for example, it could be very much in line with normal rates. In the next 2 to 3 years, we expect the tax rates to come down for sure, for sure in India, but we also expect profitability to come back to in a lot of other regions, so that could potentially bring down the overall effective tax rate for the company.

Bino Pathiparampil: Thank you very much and best of luck.

Moderator: Thank you. The next question is from Damayanti.

Damayanti Kerai: Hello, am I audible?

Moderator: Yes.

Damayanti Kerai: Thanks. Ramesh, you have been mentioning about some cost initiative, results of which will be hopefully visible in the coming quarters. Can you a bit elaborate like which are the areas where we are expecting significant cost benefits to come in, where you have been working for say the last few quarters?

Ramesh Swaminathan: We have been working on a number of initiatives, and as I've said a few minutes ago, we have been working on actually on the direct cost also in terms of alternate vendor development, in terms of routes to synthesis. Apart from that, we have been working on optimizing the workforce at the factory level, addressing the footprint to reducing the overall idle time. We're looking at the footprint rationalization also.

Apart from that optimization of the workforce at the R&D level, and a host of other measures to ramp up the productivity of the sales force and the like. And apart from that, there is, of course, freight, in terms of the mode of transportation to America. The FTS issues that we were facing in the past, then, of course, the stock returns. So how do we actually make sure that the returns were also kind of brought down, the quantum of returns in America itself.

So, all of this is actually moving in the right direction. There has been tremendous progress in this, and over the next in a year, you would see all of this certainly contribute to the EBITDA margin improvement that I'm speaking about.

Damayanti Kerai: So, say like Spiriva comes by end of this fiscal, and all these initiatives start yielding results. You're hopeful that by next year, your margin should be definitely better than 16% or so, maybe like moving to high teens?

Ramesh Swaminathan: Yes, that's absolutely true.

Damayanti Kerai: Okay. And just a question on the marketing team in the U.S. So right now you do not have any team for promotion, right? And if required, you might build a small team for the acquisition, which you did recently?

Vinita Gupta: Yes, at present, we haven't planned to build a team to promote the products. They haven't been promoted for couple of years. So we expect to continue to deliver the revenues that we have planned without an investment, but we will assess if it makes sense to invest into sales promotion.

Damayanti Kerai: Okay. So, after Solosec team disintegration, right now you do not have any specialty team in the U.S. right, if my understanding is correct?

Vinita Gupta: We don't have a specialty sales force. We promote Solosec through a partner, through Exeltis, and likewise have the option of promoting also Xopenex through a partner if we wanted to.

Damayanti Kerai: Okay. Good to hear that. My second question is on respiratory franchise. So obviously you have done very well in the Albuterol franchise. Can you talk a bit about your progress in Fostair, like what has been pick up on the European market, if you can quantify any number there in terms of sales or how you have moved in?

Vinita Gupta: Yes. So, it has ramped up. It's still, compared to the Albuterol contribution, it is relatively speaking very small given that the U.K. market itself is a fraction of the overall Fostair market, but our market share has ramped up to double-digit at this point and continues to ramp up week-after-week. We expect to launch the product into other markets in the last quarter of the fiscal year based on our launch date agreement. So we would expect to expand our position with Fostair beyond U.K. into other markets in the quarters to come, that will also help us really access larger part of the market. But the product continues to be a very good contributor to the U.K. market, the U.K. business grew significantly on a small base, but primarily on the back of Fostair.

Damayanti Kerai: Okay. And my last question is, how do you see R&D moving from here on? And what are your priority segments?

Nilesh Gupta: Yes, the R&D number is pretty stable, and we expect it to continue more or less at this level. Obviously, the high investment areas are areas like inhalation, injectables, then some biosimilars, and obviously a steady portfolio of the oral solids, ophthalmic kind of products as well. Over the period of the last few years, we've obviously changed from focusing primarily on oral solids to these differentiated dosage forms and our intention would be to continue that. I think the budget is pretty well set as you've seen, I think last couple of years we basically stayed at this kind of number, including the number that we reported this quarter as well. We feel that this is a really good number for us to be able to work with.

Damayanti Kerai: Thanks, that's helpful.

Moderator: The next question is from Sameer.

Sameer Baisiwala: Hi, Good evening everyone. Ramesh, if I'm not wrong, I thought the exit EBITDA margin for fiscal '23 you had earlier guided to 18%. I think they are very different numbers being spoken off in this call.

Ramesh Swaminathan: If there's going to be a function of larger products, Sameer, so it could be anywhere between 16% to 18% range, at the lowest, it could be 16%, at the highest level, it could be 18%, which would be the exit run rate in the fourth quarter.

Sameer Baisiwala: Okay, this is fine. And this follow-up to that is, what's the expectation for fiscal '24, both on the top line growth, excluding Spiriva and margins, including everything, if you can just help with that?

Ramesh Swaminathan: So as I said, Spiriva, is certainly going to be a very important addition to our overall portfolio. So, the overall evolution on the margin plant would certainly be dependent on that. Whilst we make progress on various initiatives that we just spoke about, getting the top line moving is going to be extremely important.

Sameer Baisiwala: Ramesh, the question is excluding Spiriva, what could be the top line growth for fiscal '24? I mean is it going to be mid-teens or any guidance on that?

Ramesh Swaminathan: It would be difficult to kind of estimate at this stage because there are several moving parts in America, including, in fact, the OSD business being what it is and so on. I would say that there is secular growth across various other geographies. But the 1 factor, which is very difficult to kind of estimate is indeed America. We have seen in the recent past at least that there has been a lot of surprises coming in. So, Spiriva is going to be a very important factor, whilst we are, of course, working on rationalizing our overall portfolio itself, make sure that there is optimization on the cost associated with the running our American business.

Sameer Baisiwala: And just on Suprep, Vinita, if my number is correct, I mean, is it a $30 million, $35 million kind of opportunity over a 6-month period? And after that, then it gets very competitive?

Vinita Gupta: Yes. So, I'm going to stay away from a product-specific guidance, but it is a nice size product. And right now, it looks like we share the market, of course, with the brand. They preemptively launched an authorized generic. But we've got close to 50% share from customers that we have locked down with the product, the market share that we have got from a customer's perspective. We also think that the exclusivity might be a little bit longer based on what we have learned from a supply perspective, we believe that some of our competitors might be delayed, and we might have the product the runway a little bit longer than 6 months**.**

Sameer Baisiwala: And one final question with your permission, given that Spiriva is so important, anything on the supply chain, different components, anything that you think can make a difference? Or are you thinking it's more or less streamlined?

Vinita Gupta: No, we have been working pretty much for the last couple of months ensuring that we have adequate supply of everything that we need, whether it's the capsules and the devices and all of it to ensure an effective launch. So, we are well into launch mode from a supply perspective.

Sameer Baisiwala: Okay, Great. Good luck.

Moderator: Thank you. The next question is from Kunal.

Kunal: Hi, Good evening. Vinita, just one clarification on the Tarapur API warning letter. I think the warning letter states that you're suspending production of drugs for the U.S. market. But I think you mentioned on the media that I think the supplies are continuing. So, just a little bit of a confusion here. If you can just clarify that?

Vinita D. Gupta: Yes, I'll let Nilesh take that question.

Nilesh Gupta: Yes. So, we've clarified to the FDA. Basically, there is a misunderstanding basis what we had shared with FDA. There were certain products that we had suspended in the past. And the misunderstanding was that we are suspending supplies from the plant altogether. So, we've clarified and we have FDA's acknowledgment on the clarification as well. We obviously continue supplying multiple products, many products. Tarapur is pretty important in the U.S. scheme of things. And we also don't anticipate any disruption of supply from that facility.

Kunal: So, of your outstanding filings, how dependent would you be on Tarapur?

Nilesh Gupta: Nothing really. There's no meaningful pending approval from Tarapur.

Kunal: Okay, got it. And second question is on again Spiriva, now I think the Spiriva prescriptions, I believe, have been falling over the years. And after the introduction of Respimat I think they have gone down even further because I think Respimat has taken 50% or so of the market. So, just wondering what's the covered market that you are actually targeting? Would it be around $500 million and maybe you're aspiring for 20%, 22% kind of market share?

Vinita Gupta: No. So, I think you can take a look at the IMS revenues and we target the entire market when we look at the brand pricing and what price we launch at. When you look at the net sales after the rebates for a brand that's more relevant for the brand than it is for generic. So I mean, the IMS revenues are still $1 billion or close to $1 billion product, it's a material product where we expect to be a sole generic with maybe an authorized generic in the near term future. We'll see what happens when the product goes generic. We have seen in cases like this where brand has shifted the franchise to a new dosage form that sometimes a lower-priced product is able to take some of the share back. So, we'll wait to see that. But it continues to be a sizable opportunity for us in the next couple of years.

Kunal: And if I can squeeze in just 1 more. On the biosimilar front, I think you have a couple of products in the U.S. market, pegfilgrastim and ranibizumab, which is still under, I think, clinical trials. I mean the market might be set up by the time you enter, just wondering how we should sort of look at these opportunities?

Vinita Gupta: Yes. So, ranibizumab is, of course, in development and pegfilgrastim, the PFS is what we were expected for by the FDA in the last couple of weeks. So, we're actively looking at ways and means of leveraging that product once we get approved in the marketplace, whether it is through institutional sales force or through a partner, we have both options, and we are actively looking at both opportunities based on, again, the investment in commercial infrastructure versus the upside.

Kunal: And you still think it could be meaningful opportunity for you because the price erosion has been very steep in biosimilars in products like pegfilgrastim in the U.S?

Vinita Gupta: Yes, so we're tracking the pricing very closely. Obviously, both on pegfilgrastim and ranibizumab as well as other products. And as the market uptake has improved, competitive intensity has increased. We have certainly seen significant price erosion. That's why we are weighing options. Like I said, we have options of both partnering or leveraging our institutional infrastructure that we will have in place for injectables to be able to gain market share with the products. I mean it's a different situation that

pegfilgrastim and ranibizumab, ranibizumab is a few years away, pegfilgrastim is in the next 6 to 12 months. So also, we will weigh the launch of the next product after pegfilgrastim to determine what makes sense for us.

Moderator: Thank you. Next question is from Surya.

Surya Patra: First question is on the R&D spend. So, you had indicated about hiving of your NCE research and hence, to some extent in using our R&D spend on the basic research front. Any update on that?

Nilesh Gupta: Yes. So, we've been trying, of course. So in essence, we've been looking at multiple options there. I think the first option was to spin out oncology altogether, transition the entire engine into an engine that produces oncology assets. It's obviously been a tough financial market at this point in time. And so we decided to focus primarily on the development assets that we have. We have 5 development assets pretty much all in the oncology space. Those are the ones that we're taking ahead. And in the meanwhile, we've scaled down the NCE team. So, we've reduced the burn very significantly. And the primary burn going forward will be the investment into the clinical development of these 5 assets.

Surya Patra: But that will not have any meaningful spike in the overall R&D spend then?

Nilesh Gupta: No. So, we see a reduction right now, first of all, because the last quarter, it was actually there in the numbers. So in Q3, Q4, we will see a reduction in the R&D line on count of that small, but it will happen. We don't see a material increase. So, I don't think we were going to get into a deep global clinical development on these yet. So, in any case, these are really Phase I assets. So, they will go through that process, they'll go through certain clinical trials before meaningful investment will come up.

Surya Patra: And secondly on the diagnostic investment, so we have not spoken much about this diagnostic foray. But we have already created a kind of price raise in that business space. So could you share that, what is the kind of cost that we are currently incurring on that side? And to what extent margins are suppressed because of that?

Nilesh Gupta: Yes. So, the business is small right now, and that's the reason why we've not been talking about it. We said we'll let it go to critical mass before we really talk about it. The investment is also not heavy and it's already fully baked into the numbers. We don't see really an increase in the burn that will happen than what is already captured in the numbers. We'll really let the business grow for the next 1, 1.5 year before we talk about it. It is performing well ahead of our expectations, well ahead of their own business plan as well. But I think we need to let it grow for some more time before we really start talking about it.

Surya Patra: Sure. Just 1 more question on the, let's say, the India business, which has been kind of, let's say, sub-par in terms of growth. That is one. And the other emerging market and ROW market in the Europe and all those are kind of doing relatively better in terms of growth. So on this market, how do you see that, okay, when you are expecting there is a profitable progress for your company as a whole, the role of these market and your aspirations in these markets and your strategy. So, in what manner these markets are going to contribute to your profit and progress of Lupin?

Vinita D. Gupta: So, I think we talked a little bit about it. But when you look at other emerging markets, it's roughly 11% of our revenues. You look at the other developed markets, roughly 10% of our revenues, both growing extremely well. The emerging markets, whether it's Latin America, South Africa, Philippines, grew double-digit and it's a profitable business at an EBITDA margin well above the company average, and we continue to drive growth in the emerging markets, look at opportunities opportunistically again, look at what we can help grow them faster.

But are looking to find ways and means of growing their emerging markets, other emerging markets of the entire pie. Likewise, the developed markets are roughly 10% of our revenues, and that's Canada, Australia and Europe. Out of which Australia is the largest now. I mean done extremely well. I think that region probably was the fastest growth part of our business in this first quarter.

And one, because we had the integration of Southern Cross in Australia. Two, we had products like Fostair growing the U.K. business and the like. And our Canadian German business also performed pretty well. I mean, the developed markets, I think, really have really good growth drivers that have a synergy with our U.S. market.

So, when you look at the inhalation pipeline, when you look at the complex injectables pipeline, when you look at our biosimilars pipeline, there's significant potential in all developed markets. So, our inhalation plans are global, especially for the developed markets, it's material opportunity. Likewise, the injectables and biosimilars. So, we expect the other developed markets to grow very nicely in the years to come as we evolve our pipeline and bring these complex platforms effectively to market.

Nilesh Gupta: And if I can just add on India, that's obviously our largest market at this point of time. And we're very aggressive about our growth prospects in India. We're substantially adding to the sales force. At this point of time, we are obviously launching multiple new products and new divisions as well. So, that double down on India will continue. Yes. Surya, you might be on mute.

Surya Patra: On Enbrel, if you can tell us whether it has reached some size of $10-odd million kind of size or isn't that. Some sense on that would be useful.

Vinita Gupta: Well beyond the $10 million plus size at this point.

Moderator: The next question is from Tushar.

Tushar Manudhane: Just on Xopenex, if you could just help understand the kind of market share this would be having in levalbuterol as a molecule?

Vinita Gupta: It's 100% of the levalbuterol market. Xopenex is levalbuterol.

Tushar Manudhane: Secondly, on the Spiriva, like any particular reason that after addressing the queries there is to be again refiled as a priority product, refiling. I presume this would have already done earlier and that would have what triggered inspections and the other regulatory actions by the U.S?

Vinita D. Gupta: Yes, whenever you file a response to a CRL you'll to get priority review, you have to file for priority review.

Tushar Manudhane: I thought it would have been more from the U.S. FDA side to determine whether the product would be taken on the priority basis or not, so that's a question.

Vinita Gupta: No. I mean, you have to file with a request and then they'll respond.

Tushar Manudhane: Thank you**.**

Moderator: The next question is from Vivek.

Vivek Agrawal: My question is on Darunavir. Can you play share some light on the product because there are multiple forms, tablets, suspension, et cetera. So, what exactly we'll be launching? And will you be having sole exclusivity on this product? Or is it going to be shared with some others also?

Vinita D. Gupta: Yes. So it's a material product. It's a tablet dosage form that we will be launching. And we have exclusivity. I believe you have assumed that there'll be an authorized generic in the marketplace. But needless to say, it's a material opportunity.

Vivek Agrawal: Would you like to highlight what is the addressable market size?

Vinita Gupta: I think it's around $300 million, if I'm not mistaken.

Vivek Agrawal: Second question is on the respiratory pipeline as well as some of the complex injectable products. Can you talk a bit more there? Are these products in terms of planning, how long for example, these products are away from filing etcetera?

Vinita Gupta: Yes. So, we have multiple products in the pipeline on the respiratory front, on the MDIs, DPI and soft-mist inhaler. At the forefront will be products like the DPIs, Ellipta franchise and the soft-mist inhaler, the Respimat franchise. And we are in different stages of development, in some case, pilot PK studies and in other cases, earlier stage.

But I would expect that we will start filing the DPI and SMI products in the next, I think you'd see 1 filing in the next year and then a couple more the year after. We also have a few MDI products that we are pursuing. And you will see those also will be filed in the next couple of years. So, I'd say a number of these, we have 9 or 10 products in the pipeline that are all in active development to be filed in the next 2 to 3 years.

Vivek Agrawal: And on some of depot products that you were developing, how far these products in terms of filing?

Vinita Gupta: Yes. So we made significant progress actually on the depot front with the first one Risperdal Consta out of our Netherlands platform facility. We have got a positive endpoint study, PD study that we completed successfully earlier this year in the last couple of months and are expecting to file that this year, end of this fiscal year.

Vivek Agrawal: Last question, if I can squeeze. So, India this year has been impacted because significant competition in some of the products, especially in diabetes, how we see the growth next year? It is possible to grow in double digit. Any color would be helpful.

Nilesh Gupta: Yes, we should be back to the double-digit growth next year. So, I think diabetes will still continue to be suppressed even next year, but on the back of growth on the other chronic areas like respiratory, on the cardiac segment itself, even other segments like GI and the like, we certainly would get back to double-digit growth.

Vivek Agrawal: Thanks.

Moderator: The next question is from Krishnendu.

Nilesh Gupta: Krishnendu, I think you are in mute.

Krishnendu Saha: Hello, can you hear me?

Nilesh Gupta: Yes.

Krishnendu Saha: Hello?

Nilesh Gupta: Go ahead.

Krishnendu Saha: Do you hear me?

Nilesh Gupta: Yes.

Krishnendu Saha: Hello, can you hear me?

Vinita Gupta: Yes, we can hear you.

Nilesh Gupta: Maybe we go on to the next one.

Moderator: The next question is from Bharat.

Bharat Sheth: Hi, thanks for the opportunity. So sir, just wanted to understand, partly on the cost containment measures, in last quarter, we outlined that we are going to save around INR 500 crores to INR 700 crores in the ensuing years. However, whatever we have detailed out in terms of the things which we are working out to contain the cost, doesn't seem to add up to save around INR 500 crores, INR 700 crores. So, what is the exact reason? Because just changing the vendor or something will not lead to a INR 500 crores of savings. So, what exactly we are doing to do that, achieve that number?

Ramesh Swaminathan: The savings are across various buckets. So, there is a portion which is actually going into the gross margins also because of the various initiatives that we have taken. So, whilst we actually started outlining in fact, our other cost measures below that line and we spoke about several things, including idle time, work-force planning, we spoke about trade, we spoke about stock returns, FTS and the like. Action on all of those have actually been going through that over the last several months, so to speak. Some of these have actually started flowing into the various lines, and there will be more to come in the days to come as well for sure.

And there have been some offsets. Essentially, as I was saying, whilst the workforce planning, for example, there has been a reduction on the salaries, on the manpower cost. There has been shifts from potentially from some other lines, that doesn't actually kind of reveal what kind of savings that we have been able to bring about. But I'm sure that the overall target is very much within our reach, and we believe that it will come out when all of this will actually pave the way for potentially the optimization that we spoke about**.**

Bharat Sheth: So, in your assessment, how much we have already achieved and by when we can achieve this exit INR 500 crore to INR 700 crores? Whether it is something which will be achieved towards the end of next year or how it is?

Ramesh Swaminathan: So, we went about wanting to achieve close to about INR 750 odd crores. And by the end of this fiscal, we think close to about INR 400 odd crores would be achieved.

Nilesh Gupta: But Ramesh, I think the point that you're making is that there are inflationary price increases, there are sale price reductions that happened. Obviously, some of the delivery that's happening right now on the numbers is happening because of that optimization, but a good part of that gets eaten away by inflationary measures as well.

Ramesh Swaminathan: On the gross margin front for sure and other parts as well. Yes.

Bharat Sheth: Nilesh, last quarter, actually, you mentioned that we'll be clocking double-digit margin irrespective of the new launches. So, how do you see that comment paving out for us?

Nilesh Gupta: Yes, unfortunately, didn't work out that way, right? So we very clearly thought that we'll get that bounce back in both the cardiac space and the diabetes space. Cardiac has improved a little bit. I think pretty much back to 10-odd percent. Diabetes continues basically at 2 percentage points growth for us.

Bharat Sheth: I'm sorry, actually I was referring from the margin perspective.

Nilesh Gupta: I'm sorry.

Vinita D. Gupta: Double digit margin.

Nilesh Gupta: I think we've said this many times over, right? I think for getting back to double-digit margin, we are, first of all, already there. We're going to have a sequential increase in the quarters on the margin as well. To get back to that 18%, 20%, certainly, we see that happening next year, but we see it on the back of the new launches, and we at least see 3 interesting products that we will be launching in the U.S. in the next year. So obviously, next year, we get back to that 18%, 20% kind of number. We're hoping that it happens in Q1. But if not in Q1, I think likely, at this point of time, Q2 onwards, we should be at significantly higher margin numbers.

Bharat Sheth: So, I just wanted to understand, without new launches, can we go back to margins like 12% or 13-odd percent or it will be all delivered by the new launches. So, I just wanted to understand.

Nilesh Gupta: So, I think when we talk about sequential improvement in Q3, Q4, we'll get to those kind of numbers without the new launches.

Bharat Sheth: That's it. And on the part of India expansion, so what sort of sales force expansion, which we are doing? So, how many sales force we have and how many we are adding?

Nilesh Gupta: So we have about 6,000 representatives right now, about 7,200 people in all. And this year, we will add another 850 representatives by the end of the fiscal.

Bharat Sheth: And what sort of cost escalation that will lead to overall?

Nilesh Gupta: I think it's baked into the numbers that we have planned. I don't have the number off-hand because basically, it's really getting those people ready for the next fiscal. In the last 2 years, we've obviously not added much to the representatives. In the top 10 companies we're possibly the second smallest in terms of sales force size. So, I think there's significant room for expansion that we see. So, there will be at least 4 more divisions that we'll be launching with this new sales force addition.

Vinita Gupta: So, it's fair to say that we will continue to improve our margins in the next 2 quarters despite this investment and we believe this investment is material for us to get the India business back to the double-digit growth.

Bharat Sheth: And before I move back to the queue, I just wanted to clarify one thing. When we said that we are going to get back to 12%, 13% margin in the third quarter and fourth quarter, here we are including Suprep, right?

Vinita Gupta: Yes, we are. Okay. I think we're on time.

Nilesh Gupta: I think we're out of time. Maybe one last question.

Moderator: Yes. The last question is from Krishnendu.

Krishnendu Saha: Can you hear me?

Vinita Gupta: Yes, we can.

Krishnendu Saha: Just a couple of understanding. The flu season is on in the U.S., it's better than the average for the last whatever historic. Just trying to if you can give us a flavor as to how it would look like in the past, some on the historic basis, how much it could add in the coming, say, year or so? And how long does it last? That is one.

Number two, I believe 20% to 25% of our Indian revenue is on in-licensing basis. So, how much of it would come for repricing or rebidding like we lost Cidmus to Dr. Reddy, if you can let me know that? And Dulera inhaler, which you said is '24, just to clarify how big is the market? Those are 3 questions.

Vinita Gupta: Yes. So, the first question on the flu season, it's hard to predict given that 3 years we've had no flu season. But it's fair to say that we have started to see some pickup, both in the U.S. as well as what we're hearing from our team on the API side. They're seeing the Cephalosporin business pick up. It's hard to really put a scale and around it. But it's fair to say that we should be able to do better than the past couple of years. And this season will really establish what it looks like going forward. Usually, the flu season lasts from October

onwards till April- May. So, it varies from season to season. So, we'll see where we end up. But we are looking forward to a strong flu season and serving patients in a strong flu season.

Krishnendu Saha: Is that number baked in when we speak about margins or the top line in the U.S? Is that a number we take into account or we just as usual, we take in the last 2 years' figures?

Vinita Gupta: Yes, we have. Albuterol, Cidmus and the in-license product.

Ramesh Swaminathan: You said 25%. It's not true. It's actually 16% at this stage. You will see this progressively coming down too much lower numbers because there is going to be loss of exclusivity coming up over the next couple of years also.

Krishnendu Saha: So, the 4 divisions which we launch and 2 more would take care of the falls, which would happen in the coming years?

Ramesh Swaminathan: Yes. And also we expect, in fact, the growth from our newer product that we are speaking about as well as the in-line portfolio to kind of take care of that.

Krishnendu Saha: And if you could, sorry, the third question was

Vinita Gupta: It was on Dulera, the market size, $200 million or thereabouts.

Krishnendu Saha: So, if I can just line of reduction, like it will be like Spiriva, Dulera and the HIV drug, which is going to get launched. When does that go to get launched?

Vinita Gupta: Well, we talked about Spiriva and Darunavir.

Krishnendu Saha: Darunavir, the product is launched. Sorry, I didn't get that, part, so I'm repeating the question.

Vinita Gupta: Yes, it's going to be Q1 of next fiscal is when we expect Darunavir to launch, we've already got approval, and we are first to file on the tablet dosage form. So, I expect to launch it in time. We are getting launch ready for that product as well. And then we have Diazepam Gel, which is a smaller product, but again, a significant amount of complexity. So, we expect that to be a nice launch for us in the next 3 to 6 months. And then we have Nascobal, where we are first to file out of Somerset that we hope to launch in either the first or the second quarter of next fiscal year.

Krishnendu Saha: And so Somerset is still on with us. So, we will keep the plant running and we'll keep it working just the way it was in the past?

Vinita Gupta: Actually, it is a very efficient plant now. I mean we had a lot of failure to supply out of there as well because of the compliance issues. Now that the compliance issues are behind us, the team there has done a great job in

getting the service levels up to the 98% plus, the same as India. That is what has really got our FTS, failure to supply penalties down significantly that we talked about in the last hour. And so the efficiency from the plant has gone up significantly and the new product launches will just add to what the plant can contribute to the business.

Krishnendu Saha: I'll just ask 1 last question. On Tarapur, the API plant, it doesn't have anything to do with the growth in the Goa plant? When do we see that coming through? How do we tie those things up?

Ramesh Swaminathan: So, they're unconnected. So, Goa, we'd already cleared the 483 and warning letter issues, right? In Tarapur, it's an API plant with no meaningful pending approvals. And like we've already clarified, the continuity, supply continuity remains as is.

Krishnendu Saha: So, Goa plant is not very much dependent on.

Vinita D. Gupta: Okay. So with that, we will wrap it up. I hope you have got answers to all your questions. As you can see, we are committed to deliver continuous improvement on our business as we execute on our strategic plan. This quarter certainly was a turnaround for us and we will continue to build upon this, build on the momentum in the next 2 quarters.

There were a number of questions around cost improvement measures. Some we have got significant benefit and will continue to do so in the quarters to come. And some of it will show in the margin improvement. Some will go to offset the inflationary pressures that we see. But needless to say, as we get into a period of getting approvals for some of our bigger products like Spiriva and Darunavir and the like, we expect to get to a very strong double-digit margin, 16%, 18% plus in the next fiscal year.

So, we look forward to connecting with you again and look forward to sharing updates on our business in the next couple of months. Thank you.

Moderator: Thank you. That concludes today's conference. You may now disconnect your lines.