“Lupin Limited Q4 FY2024 Earnings Conference Call”

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MANAGEMENT:

- **MS. VINITA GUPTA – CEO, LUPIN LIMITED**
- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
- **MR. RAMESH SWAMINATHAN - EXECUTIVE DIRECTOR, GLOBAL CFO AND HEAD CORPORATE AFFAIRS, LUPIN LIMITED**
- **MR. RAVI AGRAWAL – M&A AND INVESTOR RELATIONS**

Moderator: Good afternoon, and welcome to Lupin Limited Q4FY24 Earnings Conference Call. Please note that all participants' line 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 Q4, and end of FY24 earnings call. I have with me our MD, Nilesh; our CFO, Ramesh; and our Head of Investor Relations, Ravi. We look forward to sharing with you our highlights for the quarter as well as the full-year and outlook for fiscal year '25.

We are very pleased to close the year on a strong note, continuing to improve our operating margins and maintain the business momentum for the last many quarters.

Revenues in the quarter have grown 13% year-over-year driven by all major regions, in particular, U.S., India, EMEA and APAC.

Gross margins and operating margins improved in Q4, based on better business and product mix, in particular in the U.S. and also higher efficiencies.

We were very pleased that EBITDA margins improved quarter over quarter, despite higher R&D investments and Q4 seasonality impact in U.S. and India.

Our U.S. business continues strong at $200 million plus revenues, despite lower seasonal products and reduction in products like Darunavir that experienced additional competition.

Our base business performed well, and new products like Tiotropium and generic Prolensa helped offset the seasonal product decline. We are at a good level with 30% substitution with Tiotropium, 10 months into the launch. We expect Tiotropium to continue to be a major growth driver in fiscal year '25. We had 6 product launches in the US during the quarter with Prolensa Ophthalmic, Ganirelix Inj. and Cyanocobalamin being the meaningful ones.

We expect to sustain our U.S. business at the $200 million plus level, going ahead with the continued ramp-up of Tiotropium and new product launches in fiscal year '25. We have 10 plus launches during the year.

Our India business has grown 8.3% year-over-year in the quarter, and 9.6% for fiscal year '24. Within this, our India prescription business has grown 8.7% year-over-year and ex-Cidmus 9.3% year-over-year on full year basis, this was 1.2 times IPM growth. Core therapies like cardio and respiratory segments have grown well ahead of the market and we are very confident of continued 25-30% over IPM in fiscal year FY'25. We have already started to see this in April. We have also carved out our trade-generics business into a 100% wholly-owned subsidiary to enhance agility and drive focus on this high-growth segment.

Apart from the U.S. and India, other regions have performed well too. EMEA and APAC recorded strong double-digit growth in the quarter, driven by Fostair generic in Europe and strong growth in markets like Australia as well as Philippines.

We complemented our global respiratory portfolio by acquiring two accretive established brands from Sanofi for Europe and Canada.

During the year, we also closed our Medisol transaction, the French complex injectable company, which expands our position in complex generics, in particular in Europe.

On the R&D front, we have continued to pivot to more complex products, in particular inhalation and complex injectables. We spend around 50% of our R&D investments in these two platforms. Complex products today constitute around 40% of our US portfolio which we expect to increase to about 50% to 60% in the next few years.

In the fiscal year 2024, more than 80% of our new product revenues in the U.S. were from non-oral solid products. This augurs well for sustainable growth of our generic business going forward.

Switching to compliance, we have continued to build on our momentum with recent inspections at Aurangabad and Dabhasa with positive outcomes. We

are on track with our remediation efforts at our Tarapur and Mandideep Unit 1 sites and are fully committed to ensure that all our sites are fully compliant with best-in-class GMP standards.

Reflecting on the year gone by, fiscal year 2024 has truly been an inflection point for our organization.

We are very pleased to turn around our business and deliver on our promise of sustained and profitable growth, driving the shift to complex generics, getting our India business growth to 20% to 30% above market, improving our GMP compliance position and continuing to drive efficiencies. It has also been a year of growth across all our regions and business segments.

As we look at FY'25 and beyond we are focused on continuing to drive margin improvement while growing and evolving our business, building on our portfolio evolution into complex generics and specialty. We are truly excited with the potential we have ahead of us.

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

Ramesh Swaminathan: Thank you, Vinita. Friends, I welcome you all to our Q4FY24 and FY24 Annual Earnings Call. I'm happy to report that this quarter, we've delivered another quarter of strong performance with EBITDA growth of 65% year-on-year and consistent 20% plus percentage EBITDA margins.

As you would have seen, we've improved our EBITDA margins quarter-on-quarter by about 30 basis points, despite higher R&D costs during the quarter. In-fact, for the full year, we have handsomely outperformed the guidance we had provided to you last year, both in terms of growth and profitability.

Going into the numbers, sales of Q4FY24 came in at INR 4,895 crores as compared to INR 4,330 crores in Q4 last year, a growth of 13% year-on-year.

We've registered robust growth across most of our key geographies. North America has grown at a strong 23% year-on-year. India business has grown

at a healthy 8.3% year-on-year, whilst EMEA grew at 17% year-on-year. Our ROW grew 8% year-on-year and growth markets grew at 16% year-on-year.

On a full-year basis, sales have come in at INR 19,656 crores, a growth of 21% year on-year and 20% year-on-year adjusting for NCE income received during Q1 ofFY24.

All key segments, excluding LATAM have delivered strong growth. In particular, U.S. grew 29% in constant currency terms. Our formulation business excluding India and US has grown robust 20% YoY during this period.

U.S. business

During the quarter the US business recorded sales of $209 mn marginally lower than Q3 levels on constant currency basis. While pricing on base business has remained relatively flat, the decline has been due to lower volumes on seasonal products and lower sales of products like Darunavir.

For the full year, the U.S. Business has recorded sales of $850 million as against $632 million last year, registering a growth of 29% year-on-year in constant currency terms. This has been led by volume growth in our base business and healthy contributions from new products.

As Vinita mentioned, our strategy of focusing on complex products in our pipeline has paid handsome dividends, and more than 80% of the sales from our new products this year have come from non-oral solids. In fact, if you look at our pipeline for FY25, more than 70% of the new launches in the current year will be non-oral solid in nature.

India region

The India business has grown by 8.3% year-on-year in the quarter and 9.6% year-on-year in FY24. Specifically, during the year, the prescription business has grown 8.7% year-on-year and 9.3% ex-Cidmus, outperforming the IPM growth during the year.

Segments like respiratory, cardiology, and oncology have outperformed IPM growth in their respective segments. The share of in-licensed products in the

quarter has reduced to around 11% of our portfolio from around 15% to 16% last year, while also having a positive impact on our profitability going ahead.

We've launched 28 products in FY24 and plan to launch about 20 products in FY25. I'm also happy to report that our diagnostic business is scaling up very well, with revenue growth of 160% year-on-year and around 40 labs under operation.

EMEA

Our EMEA region, which constitutes our EU business and the South Africa business, registered strong growth of 17% year-on-year during the quarter, and 24% year-on-year in FY24. This has been driven by steady growth in key EU markets like UK and Germany, NaMuscla, inhalation products and also partner business.

Growth markets

Our growth market includes the APAC and LATAM regions. The APAC markets grew by 33% year-on-year during the quarter, led by strong growth in markets like Philippines and Australia. LATAM markets however, declined by 6% year-on-year in the quarter, due to ongoing headwinds in Brazil, which were partially offset by growth in Mexico.

Other operating income

Other operating income at INR 66 crores has decreased by 34% year-on-year, during the quarter. This decrease is primarily on account of the phasing of PLI benefits during the year. On a full year basis, other operating income came in at INR 355 crores against INR 372 crores last year.

Gross margins

Coming to the profitability, Q4 FY24 gross margins were 67.8%, up from 59.6% in Q4 last year and 66% recorded in Q3FY24.

Whilst we have seen improvement driven by multiple factors, which includes better product mix, lower share of in-licensed products, increased volumes,

and gross margins have also benefited from higher inventory, which we are carrying on account of risk mitigation measure due to geopolitical tensions in the Middle East. For the full year, reported gross margins have come in at 66.2% as compared to 58.3% last year. Adjusted for NCE income, gross margins are at 65.8%.

Employee benefit expenses at INR 900 crores increased marginally from INR 889 crores in Q3FY24, translating into 18.4% of sales vis-a-vis 17.5% last quarter. This change is largely attributable to higher impact of ESOPs, offset by lower seasonal domestic sales during the quarter.

For the full year, employee costs have increased by INR 407 crores, mainly driven by the annual salary hikes and the India field force expansion, which we undertook last year. This translates to 17.8% of sales on a reported basis, and 18% on adjusted basis as compared to 19% of sales in FY23.

Manufacturing and other expenses

Q4FY24 manufacturing and other expenses came in at INR 1,490 crores, which translates to approximately 30.4% of sales as compared to 30.7% of sales in Q3 this year. The expenses are lower in spite of higher R&D, due to lower business settlement expenses, lower litigation costs, lower SG&A costs due to seasonality.

Manufacturing other expenses in FY24, came in at INR 6,073 crores, an increase of INR 1,019 crores as compared to FY23. This translated to 30.9% on a reported basis and 31.2% of sales on an ex-NCE basis as compared to 31.1% last year. This has been led by primarily higher R&D outlay, higher SG&A on account of field force expansion and higher volumes from increased sales.

R&D is at INR 426 crores, that's 8.7% of sales in Q4FY24, as compared to INR 305 crores at 7% of sales in Q4FY23. For the full year, R&D is INR 1,527 crores, vis-a-vis guidance of about INR 1,500 crores to INR 1,550 crores, translating to 7.8% of sales.

EBITDA

Excluding Forex and other income, EBITDA was at INR 997 crores, up 65% year-on-year. Margins for the quarter were higher at 20.4%, vis-a-vis 20.1% in Q3FY 24 and 13.9% in Q4 last year. For the FY24 period, reported EBITDA margins at 19.3% and excluding NCE income at 18.5%.

Depreciation & Amortization

Depreciation and amortization at INR 457 crores as compared to INR 264 crores last year. This recognizes impairment of INR 201 crores relating to the intangible assets, which are essentially discontinued ANDAs, and certain tangible assets.

ETR

ETR was 26% in Q4 and 20.1% for FY24.

Balance Sheet Items

Operating working capital was at INR 5,691 crores as of 31 March, 24, which translates to 105 days of net working capital. While this has been a reduction as compared to the last year, it's increased from the 96 days recorded last quarter, primarily on account of higher inventory that we are carrying, given the disruption and the geopolitical tensions in the Middle East.

Net debt stands at INR 477 crores. It's reduced from INR 2,527 crores in March '23, indicating a reduction of more than INR 2,000 crores during the year.

ESG

On the ESG front, of course, we've done extremely well, as you'll be aware, and we have got a S&P DJSI score of 69 over 100, kind of reflecting exceptional performance, placing us at the top 95 percentile for the pharmaceutical sector as a whole.

With this, we will open the floor for discussions.

Moderator: Thank you very much, sir, for the insights. We will now begin the question-and answer session. Please raise your hands from the participants tab on the screen to ask questions.

So, the first question is from Neha Manpuria. Neha, go ahead, please.

Neha Manpuria Yes, thanks for taking my question. My first question is on the U.S. pipeline, two products specifically. First, on Mirabegron, we saw that we launched the product and then we got an injunction. How do you think is our position in the litigation, given the win in the lower court? Do you think this is still a credible launch for this year?

And second, on Spiriva, we have seen some moderation in market share in the last few weeks. So, what's your sense there? Your opening comments did mention traction in the product. So, what are we expecting in terms of market share, when we need to think about Spiriva going into next year?

Vinita Gupta: So Mirabegron, we have a temporary restraining order. They were not given the preliminary injunction. And we feel pretty good about our position and we'll have a read on it over the next few days. Hopefully, should be able to launch the product again. I think that Astellas has really filed multiple patent after patent, and to prevent affordable generics to come to market. But we feel pretty strongly about our position, both from a non-infringement as well as invalidity standpoint. So should certainly have the opportunity to relaunch the product shortly.

On Tiotropium, while we had guided at the beginning of the year, that typically in the first year, the first 12 months, you see a generic product take 25% to 30% share. And we are right now 10 months in at 30% share. A couple of weeks can be up or down, but we're not seeing any tapering off of on our order book or share standpoint. So feel pretty good about the 30% so far.

We're also going to take a look at what happens over the next couple of months. In June, the brand has announced as part of a response on respiratory products. The pressure that they had from Congress, they had announced a $35 cap on out-of- pocket pay for patients. We'll see if there is any impact of that, if it suggests that we should modify any of our strategy.

But so far, it's been pretty good. We've been pretty much on track on the share and very favourable on the pricing front as well.

Neha Manpuria: So are we still okay with the 40% market share that we had guided to previously for Spiriva in the next year?

Vinita Gupta: We have said 30% - 35%, and we'll see. We want profitable share at the end of the day.

Neha Manpuria: Yes, understood. And my second question is on the gross margins, a very strong gross margin performance. How should I think about the gross margins going into next year? Is this the base that we should assume that we build on, or should I take a more blended three-quarter for gross margins, given the higher inventory impact that you talked about?

Ramesh Swaminathan: So current quarter has of course, been influenced by the sales mix, and, of course, tailwinds on account of the input cost, and there's of course, the higher inventory build - up. I would imagine, given the buoyancy at the top line, kind of products that we are bringing in, and the emphasis on, in fact, route to synthesis, potentially alternative vendor strategies and the like, we should be able to kind of maintain the same levels of gross margins in the days to come.

Moderator: Thanks, Neha. The next question is from Kunal Dhamesha. Kunal, go ahead, please.

Kunal Dhamesha: Yes, good evening, and thank you for the opportunity. And congratulations on good set of numbers. Just the first one on the top line growth expectation for FY25 overall and the EBITDA margin expectation.

Vinita Gupta: So we should be at close to 10% level in terms of revenue growth and EBITDA margin at 20% plus.

Kunal Dhamesha: And would this EBITDA margin expectation include Mirabegron or if Mirabegron happens, there would be potential upside to this?

Vinita Gupta: Yes, hopefully we have some upside to it.

Kunal Dhamesha: And secondly, on the India business, now that we have again started growing at low double-digits, how do we see this market growth in the next year, and probably in the next two to three years, given that we have one patent expiry, which is coming, what would we do to offset that?

And as a second part of that question is, the number of medical representatives we have in the business, along with the first line manager and excluding the first line manager. Thank you.

Nilesh Gupta: Sure. So I think on the India business, our goal has been to grow at 20% to 30% ahead of the market. The market, for example, in Q4 was sluggish, grew only 5.7%, but for the year, market grew at 7.6%. So, we obviously grew ahead of the market at 8.7%.

We would want this to step up even more, so we're hoping for the market to grow at a slightly higher pace. And obviously, we should be close to double-digits growth in India accordingly. I don't have the exact specifics on the salesforce numbers. It's roughly about 7,500 med reps and 10,000 people altogether.

Kunal Dhamesha: Okay, perfect. And if I may, one more on the diagnostic business, we have seen strong growth. But how do we see deployment of capital from here on? And in terms of profitability, it is obviously a drag right now, but when do you see that probably become breakeven?

Nilesh Gupta: Yes. So I think at the Board level, we've built clear guardrails for all the adjacent businesses, whether it's the diagnostic business, whether it's the digital business, whether it's even our investments into areas like OTC.

On diagnostics in particular, the burn went up in the last year versus the previous year, so it was higher in FY24 versus FY23. In FY25, we basically see it at a similar level and then we see it coming down. So in the next two years, we see significant improvement on the business from a profitability perspective.

Kunal Dhamesha: Okay. And in terms of any revenue growth guidance for that business, the entire other business apart from the pharma business?

Nilesh Gupta: So I think we are calling it out separately in our numbers as we're reporting them now. So the numbers that are reported, I think INR 60 odd crores is basically all diagnostic at this point of time. That number will obviously grow to a multiple of that in the next five years. Still very, very small, and certainly not the focus area for India. The core pharmaceutical business will always remain the focus in India.

Moderator: Thanks Kunal. We'll take the next question from Bino Pathiparampil.

Bino Pathiparampil: Hi, Good morning, and good afternoon. Vinita, first on Spiriva, can we assume that an authorized generic is now not going to come or is it still a risk?

Vinita Gupta: It's hard to tell, Bino. We hope that given the share as well as the current status of the market that we continue as both the brand and generic, but it's hard to predict.

Bino Pathiparampil: And in Myrbetriq, you launched only the 25 mg and not the 50 mg. What was the reason for that?

Vinita Gupta: We were just prepared with the 25 mg and we were ready to launch.

Bino Pathiparampil: So if the TRO is lifted, you can potentially launch 50 as well, you would potentially?

Vinita Gupta: Yes, potentially.

Bino Pathiparampil: And just one question on the market size on Myrbetriq, as per IQVIA and as per your PR, of course, quoting IQVIA, the market size is around $2 billion. But if you look at Astellas annual report, it seems to be very different, only at around $700 million or something. Is there such a big rebate or something in there or how do you read that?

Vinita Gupta: Yes, we believe that there is that gross to net that Astellas has contracted with PBMs.

Bino Pathiparampil: And if I may push one last one, the Oracea generic opportunity, the sales number you have quoted from IQVIA of around $128 million or so, is that the market for just Oracea or the entire generic Doxycycline market?

Vinita Gupta: Just Oracea. I mean, Doxycycline is really large, many different brands. That's been a really nice launch for us in April.

Moderator: Thanks, Bino. We'll take the next question from Nimish Mehta.

Nimish Mehta: Thanks for the opportunity. See, what I understand for the U.S. generics industry, that is in the month of April, we have seen some significant price reduction across the board. One, wanted to know your views and also the impact on our portfolio.

Vinita Gupta: So price erosion actually has been pretty reasonable over the last 12 months, I would say. We experienced a single-digit price erosion, and there still continues to be a very strong drug shortage issue in the U.S.

We were just in Washington D.C. last week, along with a number of our peers, and heard a lot of concerns about drug shortages. So we expect that should really keep price erosion at a reasonable level going forward, at least in the next 12 months. So we don't really see this April impact. You probably are looking at IMS data, which really does not give you a real picture of net pricing.

Nimish Mehta: So the reduction that is seen in April is not something that is not seen on the ground, is that what you're saying?

Vinita Gupta: Yes. We haven't. Like I said, in the last 12 months, it's been a single digit.

Nimish Mehta: The other question I have is regarding the domestic market. We have seen government cracking down on a lot of the smaller CMO suppliers. So we wanted to know how is it impacting Lupin? And will that also mean that we will have more capacity to build, so that we kind of do not get into any problem related to CMO quality issues or anything like that?

Nilesh Gupta: Yes. I think that's a great question. Clearly, the government is showing intent to move up on quality, which is why they've been cracking down on some of the suppliers, you would have seen today, they talked about new standards for exports as well. So I think there is a clear intent to move up on quality, which is great for companies such as us. We've not had any disruption with

any of these. Most of the suppliers we've not worked with, or we've had mitigation plans in place, as these issues may have arisen as well.

We have a pretty robust process of vendor management in place, so not impacted. I think there's a bigger opportunity in the longer term to manufacture more ourselves, and that's something that we will explore.

Nimish Mehta: And if I may, the last one on the trade generics, that will be very helpful. I mean, we have seen all the large companies including ours, to be launching a separate trade generics business, either in the form of a company or a division. So what is that trigger? And how do you think this will play out, again, versus our own brand? So do you think that at an aggregate level, this will grow significantly enough to kind of challenge the pricing for the whole of industry?

Nilesh Gupta: So, I think the trade generics is a growth opportunity. Clearly, it's a higher growth segment. That being said, it's going to remain a portion of the market. It's not going to be the dominant portion of the market. And our focus, just like others, would be to bring that focus, bring that agility, bring that clear accountability into managing that business very closely.

This business has to be managed very closely. It has to be managed much more aggressively than even the India domestic business. And I think that was the main reason to spin it into a separate entity. But again, just like with anything else, there are guardrails that are built into this, and we don't think this is going to be the dominant element of the Indian market.

Nimish Mehta: But I just wanted to know, what is the trigger for which it will grow? Because it has been there since many years now, right? So what is the change that has happened in the market, which you see is going to trigger the growth in this generic business?

Nilesh Gupta: I think whether it's organized retail, whether it is the hospital segment, whether it's more institutional buy, obviously, there is more of this business happening there. And therefore, that is the opportunity as well, including to Tier 2, Tier 3 kind of towns as well.

Moderator: Thanks, Nimish. We'll take the next question from Shyam Srinivasan.

Shyam Srinivasan: Good evening, and thank you for taking my question. Just the first one on the U.S. business, right? So we have done an annual revenue of $815 million. And just want to see how we should look at it in a medium to longer term, can we go back to $1 billion at some point of time? What are some of the drivers of that particular thing? I think that's the first question I have.

Vinita Gupta: Yes, so certainly, with the pipeline that we have over the next two years, next year being both a combination of some of these PIV products, where we should have some upside opportunity, and some nice injectable products as well. The following year, potentially the launch of Tolvaptan, which we are exclusive generic. That plus our injectable portfolio, products like Liraglutide, Victoza, Saxenda, Glucagon, we expect fiscal year '26 to be certainly a year where we have, if not at a billion, we should be close to it.

Shyam Srinivasan: Understood. It's still close to what about 10%, 12% kind of growth, right? Won't we see a more faster growth? I'm just wondering why not?

Vinita Gupta: So, we still assume that all the products will come down. We still assume in our plan that we will see additional competition on existing products, that new products offset and help grow. So hopefully, potentially, there's an upside if you don't see that kind of price erosion.

Shyam Srinivasan: The second one is on the 80% of new products are non-oral in nature. If you were to map the margins on that portfolio, vis-a-vis say the orals, should one actually expect higher margins or you think even non-oral margins have actually come down to what about the 20% odd that you're showing? How should we look at that?

Vinita Gupta: No, definitely much better margins. That's what helped us really shore up the U.S. business profitability, and the company profitability as well to a certain extent. The complex products are relatively speaking better margin products.

Shyam Srinivasan: Just trying to tie this to the guidance then, so last question for Ramesh. When we talk about gross margins not improving further from here, but all this contribution on non-oral continues to remain in the forward path. So just

trying to tie, gross margins, we should see benefit, but we might give it back elsewhere is it? Is that how we should look at it?

Ramesh Swaminathan: There is going to be a higher quantum of R&D spend. It's kind of reflected in the current quarter itself. So about INR 450 crores, so that run rate certainly would be there. And whilst, of course, there would be improvements in the gross margins front, there are also tailwinds. If you look at, for example, the freight element, there's uncertainty there and so on. So we can't actually provide for all kind of ups and downs in the future. So to that extent, would prefer to be prudent in our guidance also.

Moderator: We'll take the next question from Surya Patra.

Surya Patra: Ma'am, first question is about the Spiriva. So how should we think about the pricing of Spiriva or how sustainable is this pricing, given the kind of cap on the overall cost that you've mentioned?

Vinita Gupta: So far, it's been very stable. The price based on the brand price and the minimal amount of discount that we had to give to be able to get substitution. And we will see what the brand does. We'll see the impact of the change in coupon that is expected to come in June, and determine if we need to do anything more than that. But at this point in time, it feels -- it looks like it's very stable.

Surya Patra: In terms of the list price calculation for the brand, have you seen any change in the initial period of this quarter?

Vinita Gupta: No, we haven't.

Surya Patra: So is it fair to believe that the list price is likely to be maintained for the entire year?

Vinita Gupta: I would expect so. We don't have any indications. Of course, the brand can do what the brand wants to do. But they typically don't change the list price.

Surya Patra: Second question is about overall respiratory sales contribution to the business. So is it possible to share what is our respiratory sales mix for the U.S. business, and what it is in general for your overall Lupin-wide business?

Vinita Gupta: So company-wide, it's at 25%, given the strong presence in the U.S., India, and Europe, and also growing presence in other countries. We just launched Tiotropium in Canada. We are launching it in Australia. So 25% company-wide, the U.S. is close to 40%.

Surya Patra: And this quarter, it looks like that we have seen some sequential uptake in the Albuterol market share. So could you share what is the market share currently that we're enjoying? And what is your outlook there in terms of pricing as well as in terms of the competition that you might face further?

Vinita Gupta: It's pretty stable at that 23% level market share. There's been some uptake because of seasonality in the past couple of months. But it's tapered off a little bit because the flu season was short, and it's been fairly stable.

Also from a competition standpoint, it's a very difficult product to make. It's not easy to make the MDIs and DPIs as we find as well. So we hope to see more stability in this portfolio.

Surya Patra: While you've mentioned that, going ahead by FY28, you are likely to introduce many complex products, around 20 odd products over three - four years. So given those kinds of pipeline, where do you see your respiratory portfolio playing for your overall growth strategy?

Vinita Gupta: It's a significant growth driver for us for the next five years. As we look at our five-year plan, I mean, both the respiratory and injectable products have increasing percentage of our investment. They're going to be a larger part of our portfolio going forward.

Surya Patra: Just last one question. If you can comment on the Lupin Life Initiatives along with the diagnostic, and that is helping your domestic portfolios, domestic business as a whole. So how, all these are integrated and how are these going to help you in the domestic positioning?

Nilesh Gupta: That's the question that we ask the team regularly as well. I think when it comes to diagnostics, one part obviously is the role that key opinion leaders have played on diagnostics.

We're looking at companion medicines, between diagnostics and drugs as well. So we're looking at pathways there. So there are certain synergies, but I think other than that, obviously the bigger thing is to be a trusted provider of healthcare, which is why we have that business.

On digital, I think that is much closer to our Cardiovascular/ Metabolic play. And I think it's the same doctors, we are reaching the same target audience for an additional set of prescriptions. And hopefully, we will get substantial rub off benefit of that. That business is obviously, I think we're talking about changing doctor-patient behaviour, and that's obviously more challenging from that perspective, but we've had some nice wins to start.

Surya Patra: Could you give us some update about the Fostair inhaler market share progression in Europe, as well as what is the progress that we have seen for our Enbrel in Europe? What is the market share that we would be happy with?

Vinita Gupta: Fostair, we still have the dominant share in most of the European countries. We've launched, I think at this point we're in 13 countries, and through both our direct presence as well as our partners, and continue to really build on our share. So it's been a material growth driver for our European business this past year. It continues to be a very strong product for us, largest product for us in Europe.

Surya Patra: This is a $15 million, $20 million product, ma'am?

Vinita Gupta: More than that. Enbrel also has improved. We've had growth in Enbrel revenues this past year. In Europe, certainly, the share has grown, but we have launched also in other countries like Russia the product was launched. We also have countries like in Latin America that are on the table right now. We are launching in the Middle East and Australia, and we just announced also this last week we launched in Canada through our Sandoz partnership, so the product continues to grow in all of the available markets.

Moderator: We'll take the next question from Tarang Agrawal.

Tarang Agrawal: Hi, good evening, and congratulations for an extremely strong set of numbers. A couple of questions. One, we read a lot around shortages in the

U.S., both around injectables as well as the oral solids. There seems to be a fair bit of traction from regulators and state actors as well. But, I mean, you being there, are you witnessing anything structurally changing in this market?

Second, versus how things were, say, a year back, how have things evolved and how do you see these things moving forward? So those are two sub-questions.

And second, if you could give us some sense on what's happening with your biosimilars business? Thank you.

Vinita Gupta: We certainly have seen things stabilizing. When we looked at number of the drug shortages and analysed the root cause, the largest percentage was, they were economically non-viable. So companies like us, a number of our peers had gotten out of these products, because they were just, from a pricing standpoint, had come down to a level where it didn't make sense to continue to manufacture them.

So there's been a good amount of recognition of it, both with our customers as well as the other stakeholders, the U.S. government, the FDA, the FTC, there's been a good level of concern across the board in the U.S. on these drug shortages and the cause for drug shortages. And, we think that's the reason that price erosion has stabilized to some level. And, we're going to hopefully continue to see this going forward.

Structurally, I'd say that there are a lot of stakeholders in Washington D.C., that are looking hard at the reasons for these drug shortages and are working hard to see what they can do to prevent these. So, there is a good amount of scrutiny on the market dynamics that are causing companies to exit products. And hopefully, that will bring some level of balance in the marketplace or continue to maintain the balance in the marketplace, which will be promising for the U.S. generic market.

On biosimilars, our focus so far has been on development and manufacturing of the products that we have chosen to get into. We have Enbrel, of course, Etanercept that we have partnered with Mylan, which is now with Biocon. We have other partners like Sandoz in Canada, and we have the right to the

U.S. ourselves, which comes available in 2029. So that is kind of a partner product so far.

We have Pegfilgrastim that we're still waiting to get FDA approval. In fact, we just resubmitted our supplement, the CRL response. We are actually in the process of resubmitting it shortly, but believe that we are in a very good position there as well to get FDA approval. So far, we've got European, Japanese, every other regulatory authority, but not the U.S. FDA approval. That's going to be an important one for us in fiscal year '25.

And then we have other products that we have pretty far along, like Lucentis-Ranibizumab. We intend to file in fiscal year '25 to the FDA and as well as other parts of the world. So that should be a good opportunity for us on the ophthalmic front.

And then we have a couple of respiratory products that we're pursuing as well, Mepolizumab and Benralizumab, and tracking the markets very closely to see if we can try to get the products through some of the countries without a PD study.

So, we continue to build on our biosimilar platform and strategy, but cautiously, I would say, because there are tremendous amount of hurdles as well on the biosimilars front that we have seen both from a regulatory perspective in terms of what it takes to get it through FDA and other agencies, as well as market access from a go-to-market standpoint, and then at the end of the day, the contracting strategy of the brand. So cautiously building that portfolio, which will serve us long-term as a really nice additional platform that will help us differentiate our portfolio.

Moderator: Thanks, Tarang. We'll have the next question from Girish Bakhru.

Girish Bakhru: Thanks for taking my question. Vinita, you commented on Spiriva AG-, not sure. But any update on the next ANDA filer, when we can see update on the Chinese product Lannett was trying to bring?

Vinita Gupta: Hard to predict, really. We know how long it took us. It was five years. And it's a complex product to make. So we'll wait to see. We think, there's a

hurdle patent in '27, which is hard to get around. So we expect the next couple of years should be fairly sustainable.

Girish Bakhru: And just commenting again on this few pipeline products you mentioned, especially Victoza, Saxenda, none of the Indian generics have settled; whereas we have seen so many MNC companies have already settled with Teva, possibly forming the market later this year. Just trying to assess how competitive this will be in FY '26, and whether it will be meaningfully different, depending upon what device every generic brings.

Vinita Gupta: We think that it could potentially be very competitive, based on the number of companies that have filed. But just looking at how long it has taken companies to get approval, there might be very different kind of approval scenario in the marketplace that should help make it a pretty attractive opportunity. So, hard to predict really who's going to get approved when. But in the next couple of years, certainly we should see a few competitors in the marketplace.

Girish Bakhru: And last one, I mean, Dulera, Organon is still expecting a generic this year. Any thoughts on your CRL update?

Vinita Gupta: So we are still working on our response to the FDA. Our team has met with the FDA recently, had a pretty good clarity on what it would take to respond to the agency. We expect to respond this fiscal year. So we don't expect to launch in the next 12 months.

Moderator: Thanks, Girish. Can we have the next question from Harsh Bhatia?

Harsh Bhatia: Just two quick questions. One is from the Nagpur unit 2. I think so, Glucagon is launched from that plant. From the next 12 months' perspective, which of the products do you think can come from that particular plant?

Vinita Gupta: So, we haven't launched Glucagon. We have launched Ganirelix.

Nilesh Gupta: So, I think there's 5 or 6 launches that we would expect from the Nagpur plant, 5-6 filings as well. It's still in ramp up mode really, there's only 1 or 2 products, 1 for U.S., 1 for elsewhere that we sell from that plant right now,

but this is a world-class plant. So I think from that perspective, 5-6 filings and 5-6 launches is what you would expect on a steady state going forward.

Harsh Bhatia: This would be for a period of next 2-3 year period, right?

Nilesh Gupta: Yes. If at all we should accelerate.

Harsh Bhatia: And when was your last inspection for the plant, the Unit-2?

Nilesh Gupta: We were inspected 12 months ago. That was the oral solid.

Harsh Bhatia: Unit 2 as well, the injectable block.

Vinita Gupta: Injectable plant is what we're talking about.

Harsh Bhatia: And could you comment anything on Ellipta? I think so, last time we had spoken about a few quarters back that we were looking at filing the product.

Vinita Gupta: We're still working on it. Making good progress on the platform as well as the two key products. And hope that end of this fiscal year '25, we're able to report material progress.

Moderator: Thanks, Harsh. The next question is from Damayanti Kerai.

Damayanti Kerai: Just wanted to understand your big margin improvement trajectory better. So, Ramesh mentioned it's a combination of multiple factors, but if you can help us understand say how much is broadly contributed by process efficiencies which you have brought over last few years?

And what could be broader contribution coming from new launches, et cetera, and leaving apart the inventory gain which you had seen during fourth quarter. So, very broadly, you can also help us understand which are the visible pockets of improvement, which is there for you. Because last quarter, I guess you, talked about your aspiration margins, so around 22.5 to 23% for next few years. So, any commentary on that will be helpful.

Ramesh Swaminathan: Actually, you're asking far too many questions in the same breath, but let me explain ideally the way I would. Firstly, on buoyancy, it actually contributed, so for example, the Spiriva launch itself brought in about 4%-5% points, so to

speak, on the gross margins and the like. But of course, we've been working on a host of other initiatives, which actually helped out on the gross margins, essentially, in terms of route to synthesis, AVD programs, vendors, and the like, that contributed about, and over the last three, four years, I would say about 400 odd crores, though, of course, a part of this was eroded by potentially price erosion and the like.

The second part, of course, is we kind of identified a host of things that we thought were inefficiencies in the system, which has included, for example, failures to supply, we had issues in terms of air freighting, we had issues in terms of inventory write-offs, and a host of other things. So we worked on that as well.

And that, apart from, of course, what we worked on, below the gross margin line, which included the workforce rationalization schemes across factories, R&D, and the like. So all of this put together, idle time, footprint reduction in some ways, all of this contributed, I would say another about INR 400 crores to INR 500 crores.

And this has brought us to the levels that we already are in, it's around the 20-20.5% point. We have also identified newer strategies for some of these adjacencies, and businesses that you'd like to spin off on, and so they kind of rotate on their own axis, which is including verticals like potentially the API CDMO, and at some point in time, the biosimilars and the like.

If one, all of this is actually done, surely you would be, to be something to be around the 23-24% points in line with our peers, so to speak.

Damayanti Kerai: So from this exit margin rate of 20% plus, there is good headroom to go up to, say, 23%, if all these things work out for you.

Ramesh Swaminathan: Which we think will happen in the next two to three years for sure.

Damayanti Kerai: So FY25 - you guided for 20% plus margin, and then this 20% plus margin can move up to say 23% in another two years or so. Is that the trajectory we're broadly looking at?

Ramesh Swaminathan: That's a very good understanding of the situation.

Damayanti Kerai: And my next question is on a few of the peptide products, I guess, which we earlier discussed. Anything, I guess, which should be meaningful from Lupin's perspective in the next two years? So you mentioned Liraglutide, I guess, is the nearest opportunity in this space.

Vinita Gupta: That's right. Our first peptide launch was Ganirelix, and Liraglutide will be a material opportunity over the next few years.

Damayanti Kerai: From your filing perspective, like what is the remaining steps? You're done with the process. It's a review by the FDA and final approval, which is to come, or there are some pending steps which you need to complete before these products come in market?

Vinita Gupta: We have filed a while ago and expect that we should get approved hopefully soon. And based on the patent settlements and outcomes, we'll plan to launch.

Moderator: We'll take Alankar Garude next, please.

Alankar Garude: Thank you for the opportunity. First question, regarding the INR 200 crores impairment charge, how many ANDAs have you discontinued in this quarter and what were the reasons for the same?

Ramesh Swaminathan: Actually all of the ANDAs were essentially bought out items, and a lot of this resided in America. And three of those actually resided, domiciled are still in India, something which actually came out of our Anglo-French acquisition that we did in India a couple of years ago.

So essentially because of the ruling of the Indian authorities, we discontinued a couple of products. So those were the things that we wrote-off, and of course, the products that we are not selling in America. Apart from that, we also took our accelerated write-off when it came to a few assets which we're not putting to use.

Alankar Garude: And second question, would it be fair to assume that the impact of competition in Suprep will be seen more in first quarter and there was not much of an impact in the fourth quarter?

Vinita Gupta: Yes, it's been a very good, very stable product so far.

Moderator: So we'll have the next question from Nitin Agarwal.

Nitin Agarwal: Hi, thanks for taking my question. On Mirabegron, assuming the TRO gets lifted, what sort of exclusivity period are we looking at; the current state of affairs for the product before fresh competition comes in?

Vinita Gupta: It is hard to predict, but we think that, it should be two or three players in the near term in next 12 months.

Nitin Agarwal: But we do stand to get, in the current two-player market situation, last another five to six months?

Vinita Gupta: We think so.

Nitin Agarwal: And secondly, beyond this for the rest of the year, which are the other meaningful launches that you can look forward to here?

Vinita Gupta: So, Doxycycline, Oracea has been a good launch for us. Mirabegron, of course, a large one, Slynd another PIV. August is going to be a whole, read on our litigation as well as product approval. And then we have multiple ophthalmic products, including some interesting ones, like Prednisolone is a nice one.

We have a couple of products where we have settlement dates within the year, but unfortunately, we cannot share. I mean, we have two or three products like that. And we have a nasal spray product and some injectables. We have a couple of injectable products as well.

Nitin Agarwal: And lastly, any colour on, we've got a meaningful size of emerging markets now. How these markets, some of these key markets have progressed over the last couple of years, and where are they on the profitability front, some of these bigger markets for us?

Vinita Gupta: When I look at the other emerging markets, Latin America - Mexico, Brazil, as well as Philippines and South Africa, and we've done extremely well in

Philippines. It has really been a very stable, high growth business for us, and highly profitable, compared to the company level of EBITDA.

South Africa business has been a really good scale, but had got under a lot of pressure with the currency issues there, and the fact that majority of the portfolio is imported into the country. That has turned around in the last couple of quarters, and the business has started growing very nicely as well. So, South Africa is in a pretty good position, both from a growth as well as EBITDA standpoint.

In Latin America, both Mexico and Brazil. Mexico actually, we had a significant challenge last year with a facility being closed down for 10 months, which actually caused a lot of disruption in product supply. We were back to the market and with the ramp up of our portfolio. We have seen a really good resurgence of our business. So we expect fiscal year '25 to be really strong for us in Mexico. Brazil continues to be a bit of a challenge for us, and we are looking to find ways and means of, improving that business, but that continues to be a low margin business for us.

Ramesh Swaminathan: The only thing that I would add to this is essentially whilst we recognize he potential and the possibilities, there's also the risk of Forex, which can sometimes eat into the gains that we make.

Moderator: We'll take the next question from Saion Mukherjee.

Saion Mukherjee: Just a quick one. Can you share, Vinita, the number of ANDAs filed in this fiscal year?

Vinita Gupta: The U.S. ANDAs was a small list. It was six products that were filed this year.

Saion Mukherjee: And is there any reason the intensity of filing has come down this year?

Vinita Gupta: So we have started focusing quite a bit on the complex products, where you're going to see fewer filings, but more impactful files.

Nilesh Gupta: I think this year was also a repurposed year. So we do see a ramp up in the filings that will happen in FY25, where just FY24 went to kind of an all-time low.

Vinita Gupta: There's some that slipped into also the first quarter, this quarter right now.

Saion Mukherjee: So should we expect around 15-odd filings going forward? Is that, or it will be higher?

Vinita Gupta: 11 to 15, I would say. Because again, our focus is on more complex filings than the number of filings.

Moderator: We have Amey Chalke, please. Amey, you can go next.

Amey Chalke: The first question was on the spending, considering that our visibility on the product launches is quite good for the U.S., we will be having good cushion on the margin front. So are we going to up the spending on the marketing and R&D? Or you will keep the cap on the R&D and marketing spend going ahead? How would be the thinking on the spending front?

Ramesh Swaminathan: We would obviously keep an eye on all the lines. But we do recognize the potential to increase R&D a bit. And that's what we've done for the next year at least. But for sure, there will be a tight leash on all kind of costs.

Amey Chalke: Second question, if we can give clarity on the Respimat and Ambisome, we were supposed to file in FY25. How is that going?

Vinita Gupta: Respimat is progressing pretty well. And we should make significant progress this year, hopefully, file at the end of the fiscal year. It is very much dependent on supply of the devices that we manufacture outside, we don't do it in-house. But it's progressing extremely well.

Ambisome, actually, we got out of the transaction and we took a charge earlier this fiscal year '24. We were not seeing the product progress from a development perspective and with our partner, we decided to focus on Doxil that we expect to launch in fiscal year 2025, but also saw additional competition in Ambisome, so decided to repurpose that investment into other products.

Amey Chalke: On the biosimilar, product like Pegfilgrastim what were you thinking of follow-on players, who are coming now after market has been genericized so much? Is it for you, it would be a learning curve from this product or you would really want to see a substantial gain in the market share in these kind of products?

Vinita Gupta: No, I think with a late entrant, we will certainly use it as a learning opportunity for us. I mean, we certainly should have a good cost position, but would want to gain profitable share. So I wouldn't say that it's a material share opportunity unless folks get out of the market. So it's really going to be more of a learning opportunity for us.

Moderator: We'll take one last question from Tushar Manudhane.

Tushar Manudhane: Just taking this biosimilars overall how much investment you would have done in biosimilars till date? And how much of the R&D spend say for FY25 would be towards biosimilars?

Ramesh Swaminathan: About, in terms of infrastructure, we have created between INR 450 crores to INR 500 crores is the figure. And in terms of R&D expenditure, we also have this policy of partnering with in fact passive financing…

Nilesh Gupta: So it'll be less than 10%. For R&D spend for FY25.

Vinita Gupta: I think also one thing that we did not mention is in our biosimilar strategy that we're also leveraging the capability for pipeline for India, which is a tremendous opportunity for us to build especially in oncology and immunology products.

Tushar Manudhane: And just one last clarity on the U.S. Sales, while there's a good pipeline in terms of approvals as well as launches for FY25, still you have indicated that U.S. quarterly sales to sustain to $200 million, is that what you commented or I heard it wrong?

Vinita Gupta: Yes, that's what we said, because we do expect some products to see pressure like Suprep, we'll see some pressure while we continue to build on

Tiotropium and other new product launches. So, a combination of all of that we said that will get us to the $200 plus million, and hopefully, with some litigation events like Mirabegron, we should be more than that.

And then certainly going into fiscal year '26, where we'll have more exclusive, large exclusive products like Tolvaptan as well as our peptide injectables, we should be able to build it to a closer to $250 million per quarter level.

Vinita Gupta: Thank you. Okay. So, that was the last question. Hopefully, we were able to respond to all your questions. I'll just say that, it's been a very, very strong year for us as an organization. The team is all charged up with what we have delivered.

We feel like we are in a very good position, in all of our major markets, India and the U.S.in particular, but also the other developed, the other emerging markets, based on the market position as well as the portfolio position, to really drive our business going forward to where we want to go.

We certainly have, like Ramesh mentioned, that 20-23%, mid-20%s EBITDA margin very much on our radar for the next few years, and we're going to continue to work, to be able to get there while evolving our business.

So, thank you again for all your support and questions, and we'll look forward to connecting with you next quarter.

Moderator: Thank you very much, ma'am. On behalf of Lupin Limited, that concludes the session. Thank you for joining us, and you may now exit the webinar. Thank you.