



February 12, 2025



“Lupin Limited Q3 FY2025 Earnings Conference Call”

February 12, 2025

MANAGEMENT:

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



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Moderator:

Welcome to Lupin Limited Q3 FY25 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, ma'am.

Vinita Gupta:

Good evening friends, I am very pleased to welcome you to our Q3 Financial year '2025 earnings call. I have with me our Managing Director 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 outlook for the year ahead.

We are very happy to report another quarter of strong performance across our key markets both on a sequential and YoY basis. This has been backed by continued improvement in margins and profitability. I would like to highlight that our margins are the highest we have achieved in the last 5 years, despite higher investments in R&D during the period. We feel confident of maintaining our growth momentum going ahead with margins in the range of 22%-23% in the current fiscal year.

Our US business delivered strong QoQ and YoY growth this quarter with revenues at a five year high. This has been led by volume growth in inline products and contribution from new products like Mirabegron that helped us offset the anticipated competition in products like Albuterol and Suprep®. Our respiratory portfolio continued strong with higher market shares in most of the key products.

We look forward to a strong close to the current fiscal year, as well as continued momentum in the year ahead. Apart from key products like Tolvaptan, we have an exciting portfolio of injectable products like Glucagon, Risperdal Consta, Liraglutide which we anticipate bringing to market next fiscal year that should help us deliver strong growth in the year. We continue to improve our profitability in the US, led by better product mix and higher efficiencies in the base business.

We are very optimistic of our long term growth strategy in the US as it continues to evolve from a commoditized generic business to more complex portfolio of injectables, respiratory and biosimilars, to ultimately a portfolio of strategic specialty assets. We believe that our pipeline will enable us to continue to drive the shift to complex products to over 50% of our portfolio over the next couple of years.

Coming to India, we reported growth of 11.9% YoY led by growth in India Formulations business and additional tenders in our Global Institutional business. Our India Formulation business recorded growth of 9.1% for the 9M this fiscal year against an IPM growth of 8.2%. While key therapies like Diabetes, Cardiac, GI grew ahead of the market and we also increased our chronic share, muted growth in the respiratory category affected our overall performance during the quarter. We are very pleased to strengthen our diabetes portfolio by acquiring the Huminsulin range of products from Eli Lilly

and also 3 trademarks from Boehringer Ingelheim for the Indian market. We feel confident on continuing to deliver above market growth in our India Formulation business, backed by our strong portfolio of innovative medicines and in-licensed products and our extensive reach through 10,000 people sales force.

Switching to R&D, our R&D as % to sales was at 7.7% during the quarter and 7.4% for the 9M. We successfully filed Ranibizumab in EU during the quarter and are looking forward to the US filing in the coming quarters. We have an exciting pipeline, with more than 20 respiratory products and 40 injectable products in development and plan to file more than 30 ANDAs in the next 2 years, of which more than 50% will be complex products. As previously guided, we expect R&D to be around INR 1,800 crores for fiscal year 25, which would mean a significant increase in our R&D spends in Q4.

From a compliance perspective, we received the EIR from the USFDA for our Pithampur Unit-1 manufacturing facility with VAI classification during the quarter. So far this year, we have received EIRs for Aurangabad and Dabhasa and have successfully completed inspections at Somerset and Nagpur Injectable Facility with zero observations. We would like to reiterate that we are committed to ensure that all our sites are fully compliant with the USFDA and other regulatory agencies around the world.

Before I hand it over to Ramesh, I would like to say that we remain optimistic to grow our business in the years ahead. Our R&D capabilities and pipeline are gaining momentum, be it our investments in various respiratory platforms like Ellipta and Respimat or the focus on complex platforms in injectables like iron colloids, peptides, 505 b(2)s and long acting Injectables and also our growing portfolio of biologics. We are also creating some unique differentiators like green propellant programs for our respiratory franchise. As I have mentioned earlier, we also continue to evolve our innovation pipeline to ramp up our specialty business in the years ahead. We believe our approach on the pipeline front and our commercial strategy will drive long term sustainable growth for the company and also build long term value for our shareholders.

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

Ramesh Swaminathan:

Friends, I welcome you all to our Q3 FY25 earnings call. This has been another quarter of consecutive double digit growth across the top and profits lines. I am particularly pleased to highlight our EBITDA margins at 24.3% during the quarter, which is the highest we have achieved in the last 5 years. Now, Diving into the numbers.

Sales

Sales for Q3 FY25 came in at INR 5,619 crores as compared to INR 5,080 crores in Q3 last year, a growth of 10.6% YoY. On a 9M basis sales came in at INR 16,630 crores versus INR 14,761 crores last year, a growth of 12.7% YoY. We have registered robust growth across most of our key geographies. India business has grown by 11.9% YoY, North America has grown 12.3% YoY, EMEA grew 20.9% YoY whilst API grew 4% YoY.

US Business

During the quarter, the US business recorded sales of USD 235 million, a growth of 10.5% YoY and 6.8% QoQ on constant currency basis. On a 9M basis, US sales were USD 682 million, a growth of 12.5% as compared to 9M of FY24. As Vinita mentions, while we have benefited from volume growth in inline products and new product introductions, this has been offset by low single digit price declines in base products and anticipated new generic competition in products like Albuterol and Suprep®. Our respiratory portfolio continued their strong performance with high market shares in most key products like Albuterol and Arformoterol. We also continue to execute on our strategy to improve our profitability in this segment, with another quarter of strong profitability from this business. On the long term, we remain confident of consistent delivery of profitable growth through an increasing share of complex products in our portfolio. On a full year FY25 basis, we anticipate our US business to deliver double digit growth, ahead of our earlier guidance of high single digit growth in the segment.

India

The India business has grown by 11.9% YoY during the quarter and 16% YoY during the 9MFY25 period. Within this, the prescription business has grown 5.8% YoY during Q3FY25. On a 9MFY25 basis, the prescription business has grown at 9.1% outperforming IPM by 1.1X. Chronic share during the quarter was higher at 65% with key segments like Diabetes and Cardiology growing ahead of the IPM growth. The share of in-licensed products is around 12% similar to the 12% last year, which also positively impacts our profitability, going ahead.

Other Businesses

Revenues in our ex-India, ex North America Formulation businesses which include EMEA, ROW and Emerging Markets have increased 7.5% YoY to INR 1,277 crores and now constitute 23% of our sales. On a 9M basis, revenues have grown 12.6% YoY to INR 3,685 crores during the period.

EMEA

Our EMEA region, which constitutes our EU region business and South Africa business, registered strong growth of 20.9% YoY and 9.8% QoQ, during this quarter. This has been driven by healthy double-digit growth in EU markets like UK and Germany from products like Luforbec® and NaMuscla®.

Emerging Markets

Our Emerging Markets include the APAC and LATAM regions and have registered sales of INR 451 crores, a decline of 4.7% YoY. On a 9M basis, revenues grew 10.5% YoY to INR 1,456 crores. While LATAM markets like Brazil and Mexico grew in local currency terms, overall growth was impacted due to Fx in this region.

Coming to P&L.

Other Operating Income

Other operating income at INR 149 crores has increased by INR 32 crores as compared to Q3FY24. This increase is mainly due to higher PLI and export benefits during the quarter.

Gross Margins

Coming to the profitability, Q3FY25 gross margins were 69.4% up from 66.0% in Q3 last year. On a 9M basis, the gross margins are at 69% versus 65.7% recorded in similar period last year, an improvement of 334 bps points. This improvement is driven by multiple factors which include better product mix, tail winds on input costs, lower share of in-licensed products, increased volumes and also various cost improvement and efficiencies which we have undertaken over the last several quarters.

Employee Benefit expense

Employee Benefit expense at INR 984 crores increased 10.7% YoY from INR 889 crores in Q3FY24 translating into 17.5% of sales. On a 9M basis, employee benefit expenses came in at INR 2,963 crores, an increase of 14.2% YoY translating to 17.8% as compared to 17.6% of sales in corresponding period last year. This change is largely attributed to higher costs attributable to regular annual increments and business growth during the period.

Manufacturing & Other Expenses

Q3FY25 came in at INR 1,696 crores, increasing 8.7% YoY from INR 1,667 crores in Q2 FY25 and INR 1,560 crores in Q3FY24 translating to 30.2% of sales versus 30.7% last year. On a 9M basis, manufacturing expenses came in at INR 4,936 crores, an increase of 7.7% YoY translating into 29.7% of sales as compared to 31.0% of sales in corresponding period last year. The expenses are higher mainly due to higher R&D costs and higher volumes in the normal course of business.

R&D

R&D is at INR 434 crores, 7.7% of sales as compared to INR 448 crores, 8.2 % of sales in Q2 FY25, with almost two thirds of our R&D directed towards complex portfolio. On a 9M basis, R&D is INR 1,232 crores or 7.4% of sales. For the full year, we expect R&D to be around INR 1,750-1,800 crores with a significant increase in R&D in Q4.

EBITDA

Excluding Forex and other income, EBITDA was INR 1,366 crores versus INR 1,022 crores last year, an increase of 33.7% YoY, with margins of 24.3% versus 20.1% last year in the same period. On a QoQ basis, margins have expanded 51bps. This margin expansion is on the backdrop of higher gross margins and lower fixed costs during the period.

On a 9M basis, EBITDA was at INR 3,985 crores, up 42.1% YoY with margins of 24% as compared to 19% in the corresponding period last year. Putting all of this together, we believe that we should be able to deliver EBITDA margins in the region of 23-23.5% range in FY25.

Tax

As far as the ETR is concerned it was 19.1% during 9MFY25. For the full year, we expect the ETR to be around 20-21%.

Balance sheet items

Operating working capital was at INR 7,071 crores as on 31st December as against INR 5,691 crores of 31st March 2024 which translates to 113 days of net working capital as compared to 105 days as on 31st March 2024. Net debt was at INR 103 crores as against Rs 477 crores as on 31st March 2024. While we focus on increased cash generation from our business, we would also like to highlight that we continuously explore strategic allocation of our capital to ensure the long-term growth vision of the company.

ESG

In the last quarter, we strengthened our ESG efforts in both environmental and social areas through various initiatives and ensuring that our operations remain "Water Positive" year after year. Our focus on reducing Scope 1 and Scope 2 emissions strengthened which includes various renewable energy projects.

We would like to update on ESG ratings. Lupin has received a Leadership ESG Score of "A-" by CDP for Climate and Water. The "A-" rating from CDP includes Lupin's performance in environmental transparency and management. The 2024 scores for Climate and Water represent an improvement from last year's "B" rating in Climate and "C" rating in Water.

Further, we have successfully launched an ESG Supplier Assessment with a third party, encompassing our critical suppliers. We conduct ongoing ESG webinars and workshops to support our key suppliers in enhancing their sustainability capacity. Lastly, our "Lives Program" has benefitted over 99,500 individuals till date. This program focuses on providing rural healthcare services to marginalized communities.

With this, we open the floor for discussions.



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Moderator: Thank you very much, sir, for the wonderful insights. We will now begin the question and answer session.

We'll take the first question from Kunal Dhamesha from Macquarie.

Kunal Dhamesha: Thank you for the opportunity and congratulations on a good set of numbers. First one on the limited competition launches for us in US market over the next two, three quarters. We have discussed a few names. I just wanted to understand that for those names like generic Jynarque®, generic Glucagon, and probably Risperdal Consta, are we on track? And am I missing some key product here, which we might be able to launch over the next couple of quarters?

Vinita Gupta: The major products are Tolvaptan and Glucagon, Risperdal Consta and potentially Liraglutide. So those will be the key products for next year.

Kunal Dhamesha: And can you suggest the probable timelines of that? Tolvaptan is I believe is quarter one FY26 but on glucagon and Risperdal Consta, is there any update in terms of approval?

Vinita Gupta: So we are making progress on both applications with the agency and would expect that hopefully, approval sooner rather than later. But I think it'll be safe to assume that Tolvaptan would be the major contributor in the first half of the fiscal year and the injectables should ramp up in the second half very nicely.

Kunal Dhamesha: And the recent inspection at Somerset, has that anything to do with our Risperdal Consta filing? Was it a PAI?

Vinita Gupta: Yes, it was a PAI but for a suspension product, for Edaravone. The Risperdal Consta product comes from Netherlands, and is manufactured at a CMO and both were inspected by the FDA last year and progressing well.

Kunal Dhamesha: And second one on the India business. We have cited that the slow growth is primarily due to issues in respiratory therapy, and I believe the respiratory therapy growth itself was quite low despite being in a winter season. So what are the factors that is leading to the slower growth in your view?

Nilesh Gupta: I mean the market seems to be that way. I mean sequentially the number is as an absolute number up actually for respiratory, but it's been lagging for a while versus the rest of the market. Even for nine months, the market was only at 4%. We were at 3% for nine months and I mean the quarter again has been disappointing. I do think it'll bounce back. I mean we've had periods of high double-digit growth on respiratory but for the last 12-16 months, it's just been slow.

I think the focus right now from a respiratory perspective in the market has been more on anti-infectives and the like, not so much MDI, DPI inhalation kind of products. But we believe that it'll bounce back, hopefully in the next couple of quarters.

Kunal Dhamesha: Sir, in your view what would be the split of the chronic side of respiratory product like inhalers versus acute like anti-infective?

- Nilesh Gupta:** Our focus is primarily on that.
- Kunal Dhamesha:** Inhalers, right?
- Nilesh Gupta:** Yes, primarily MDI, DPI, a little bit of nebulization. That's it.
- Moderator:** Thanks, Kunal. We'll take the next question from Tushar Manudhane from Motilal.
- Tushar Manudhane:** Thanks for the opportunity, sir. Particularly first on the R&D spend, though the guidance is that it is going to increase in the fourth quarter, is there any specific projects which you would like to highlight which is going to require a higher R&D spend compared to INR 434 crores spend?
- Vinita Gupta:** Your voice was very muffled, but if we got your question correctly, you're asking about the reason for the R&D spend ramping up. A good part of it is our complex generics portfolio. It's five nasal sprays actually that we expect to file in Q4 versus the rest of the year. So majority of the spend is coming into quarter four. Also injectables, there's a good amount of increase in the second half of the fiscal year. So it's primarily respiratory and injectables.
- Moderator:** We'll take the next question from Bino from Elara.
- Bino Pathiparampil:** Just following up on that question on India. So this contribution from this tender business which has helped us show growth in that line. What's the nature of that? Is it going to be steady next year as well or will it grow or will it drop off next year?
- Nilesh Gupta:** In India on the institutional business. I mean it's been fairly flat. It's been a meaningful number. It will continue into the next year as well. But I mean, we always call out the business with and without. The India Region Formulation business, which is the domestic sales business, is 5.8% year-on-year or 9.1% for nine months.
- Bino Pathiparampil:** So this tender part of the business is likely to stay flat next year?
- Nilesh Gupta:** Yes. I mean it's a good number and it will continue with that good number.
- Bino Pathiparampil:** Second on Mirabegron, what are your latest thoughts around the litigation? Are you planning to continue selling it at risk? Any further thoughts since the last call?
- Vinita Gupta:** So no change in terms of litigation status. We continue to navigate through that process. In the meantime, the generic substitution has gone up. The overall available market has gone up and our share has ramped up nicely as well. So no real change from a competitive scenario standpoint from the litigation developments.
- Bino Pathiparampil:** And the status quo is likely to continue for a few quarters or what are your thoughts?
- Vinita Gupta:** As we navigate through all of the outcomes of litigation, I mean, we expect in the first quarter of next fiscal year to get a decision on Mirabegron 2 patent and continue to litigate the others. So definitely for this fiscal year, we don't

expect any change and then we'll determine the next fiscal year based on the outcome of litigation.

- Bino Pathiparampil:** One last question to Ramesh. We have been benefiting from this PLI-related income. How long is it likely to continue? How many more quarters?
- Ramesh Swaminathan:** The benefit is there for next three years.
- Bino Pathiparampil:** But I believe you are booking up front or so. So at the current level, how long will it continue? How many quarters?
- Ramesh Swaminathan:** So there would be a decline for sure next year. In the normal course, you would be expected to look at about INR 200 crores on an annual basis. But you have the benefit of actually taking up to a third more in a particular year alone, which we've taken advantage of this year. But obviously, it would impact on the total quantum of monies that you can claim over the next three years.
- Moderator:** The next question is from Surya Patra from Phillip Capital.
- Surya Patra:** So first of all, could you clarify what is the nature of this provision that has been created and have you shared about the specific nature of the dispute also?
- Ramesh Swaminathan:** So it's basically coming in from litigations, and we don't talk about which litigation and the like. It's a conservative provision and that's what it is.
- Surya Patra:** There is nothing to anticipate or nothing to see any kind of risk relating to the Mirabegron right now?
- Ramesh Swaminathan:** No.
- Surya Patra:** Second question is on the respiratory portfolio as a whole. If I remember right, then respiratory has become a more than 30% of revenue contributor putting all geography put together. And the current period is a kind of a respiratory pro respiratory season. So what kind of performance that you would have seen for the overall respiratory portfolio for the quarter?. We have seen moderation, let's say, in India, we have seen some kind of competition in the US relating to Albuterol to be specific. So given that, is there any risk that one should think or consider about this portfolio?
- Ramesh Swaminathan:** You know, the secular trends would kind of indicate that respiratory is going to be very important for us in America and in other parts of the globe and of course India as well. There would be some quarter-on-quarter variations and the like. And that doesn't necessarily mean that the secular trend is going to be upended.
- Surya Patra:** But this is a kind of a peak seasonal period. During that period, we are witnessing relatively underperformance. That's why the question was.
- Ramesh Swaminathan:** You can't pinpoint the reason why there is a decline in any part in India and so on. So we just take it as it comes that way. But in a general sense, our focus on the segment will certainly continue.

- Vinita Gupta:** So it's a really strong contribution both in US, Europe, Canada, as well as growing in other parts of the world like Australia. And of course in India, we have the respiratory market growth at a muted level that is contributing to the lower growth. But overall, respiratory still continues to be a major therapy area for the organization. It's an area where we expect to bring all the material generic products to market across the globe and we expect to also innovate like we have done in India with the two triple novel combinations. We continue to work on respiratory green propellants for US, Europe as well as India plus other products we have the opportunity to bring to market, brands like Xopenex® in the US that have been fairly stable. And while we have a low growth in respiratory in India, we're seeing the flu season pick up in the US again, we're seeing another peak. So the market shares on the respiratory portfolio is fairly strong.
- Surya Patra:** Last question is about the cost. It is great to see your cost optimization measures really contributing to the improved margin now, and also possibly improved margin is flowing from the improvement what we have been seeing in the US business as a whole. So there would be an element of Mirabegron which could be a positive surprise. So given that, going ahead, in the next 12-month period, what kind of a margin performance that we should see for the US business? I may not require the number, but qualitatively if you can talk something about the next year's US profitability that we are anticipating?
- Ramesh Swaminathan:** So there are some tailwinds in terms of forex which you cannot be sure about. But the focus on cost is eternal insofar as we are concerned and we have seen some good results coming in. We have seen also tailwinds when it comes to input costs. But again, as I said, there are geopolitical tensions, et cetera that are actually moving parts. You can't be certain. But I think if you talk about overall margins, I did indicate the fact that between 22.5% to 23.5% would be a good range to aim for the next fiscal as well.
- Surya Patra:** Also, are you really worried about the kind of tariff things which has been talked about? Although it has been indicated to be around 2.5% on the pharma also or any US tariff thing area of concern or uncertainty for this moment?
- Vinita Gupta:** So we are monitoring it very carefully and the industry has made a strong pitch, both from AAM standpoint as well as IPA, the tariffs will have a significant impact on the generic industry if it was implemented. I mean 70% of generic drugs for the US are imported at present, 50% of generics come from India. So there's clearly a significant role that India plays on the generic front and we've made that case with all the major stakeholders. So we'll find out with the current visit of the PM to the administration what transpires. But we are hoping that pharmaceuticals and generic drugs in particular will be exempted. And if it's otherwise, we'll be looking at other ways and means of mitigating the impact with a combination of manufacturing in the US as well as wherever possible, from a cost perspective and otherwise. We are watching it very carefully, but hopeful that the case made by the industry has been heard and the implication is understood that any tariff impact can really cause more product disruption and drug shortages which no one wants in the country.

- Moderator:** We'll take the next question from Anubhav Agarwal from UBS.
- Anubhav Agarwal:** One question is on Radicava. Vinita, which year can you launch it? Is it next one, two years or beyond that?
- Vinita Gupta:** Which product are you referring to, Anubhav?
- Anubhav Agarwal:** The Somerset where you have the PAI on Radicava?
- Vinita Gupta:** I think it's out for a good number of years. It's not in the next two years.
- Anubhav Agarwal:** Second is on the Canada - Semaglutide opportunity. Would you be in the first year of the opportunity or are you pursuing that?
- Vinita Gupta:** The team is working on it. We're hopeful that we'll be in the first wave between FY26 and FY27.
- Moderator:** We'll take the next question from Bansi Desai from JP Morgan.
- Bansi Desai:** Vinita ma'am, you mentioned about increasing our focus on the specialty business in the US. So if you could just elaborate on that. Are we talking about acquiring brands like we did in case of Xopenex® or are we also going to evaluate probably late-stage assets? So what would be our strategy here and have you earmarked any investments for this business?
- Vinita Gupta:** So we do want to build specialty as the third major arm for our global business with the US being a major focus. And assets like Xopenex® is a sweet spot for us, products that fit strategic aspirations, building on the respiratory front and ideally on market assets. But we know it's difficult to really get on market assets. So we're also looking at late-stage assets that are compelling from an investment perspective.
- And you know that we are a debt-free company at this point, so have the ability to invest for the right programs and opportunities. We haven't earmarked but are committed for the right assets to explore as well as close wherever possible, both acquisitions. Simultaneously, we are also building a pipeline in the respiratory front with the capabilities we have; on the R&D side, the opportunities that we have on the green propellant front, to take the meter dose inhalers and come up with more climate-friendly and achieving both our sustainability goals and offering a differentiated product to the patients and the market. We continue to innovate on that front on the pipeline. So a combination of both pipeline as well as late-stage assets is what we're looking at.
- Bansi Desai:** And given the biotech funding has been weak out there in the US, is it fair to assume that there are good assets that are available in the market?
- Vinita Gupta:** There's a lot of opportunities right now that if one could acquire at least a few assets that are meaningful. So really good opportunity to acquire assets.
- Bansi Desai:** Secondly on the Tolvaptan opportunity. Post exclusivity, how should we see the competition coming in? Would it be in a staggered manner and would Tolvaptan be a meaningful contributor in fiscal '27 as well for us?

- Vinita Gupta:** We expect it to have a stronger tail because it's a specialty product, REMS product. It's the conversion we expect is going to be slower than what you would expect in a simple oral solid and the tail should be longer. So we would expect both second half of the fiscal year as other competition comes in, plus into fiscal year '27, it should be a meaningful product.
- Bansi Desai:** And lastly, in terms of margin trajectory, two years out, when I just look at some of the moving parts, probably PLI would have been normalized. Jynarque® also would have been probably at normalized levels. But then again, you have certain businesses in India which are probably loss-making today and that could probably contribute positively. So how should we think about margins, say, in fiscal '27-28? Would fair to assume it would be higher than where we are currently?
- Ramesh Swaminathan:** Given the kind of products that we'll be bringing to the market, obviously the top-line buoyancy would continue. There's also the focus on cost and we have taken up a number of initiatives which would actually certainly keep that on a tight leash. And the third aspect of the entire program that you spoke about is essentially adjacencies. Clearly, we are losing about a couple of percentage points because of essentially the losses that these adjacencies are currently lapping up at this stage. But that said, over the next three years, we expect that to also turn positive. But we also have growth plans in terms of spinning it off at some point. So clearly, upward movement on the EBITDA front is certainly to be expected.
- Moderator:** We'll take the next question from Saion Mukherjee.
- Saion Mukherjee:** So Vinita, Nilesh, if you can talk about Semaglutide, other than Canada, which all markets you already filed. And if you can take us through 2026 and 2027, how should we think about the launches? And your preparedness in terms of formulation and API? And how much will be the dependence on partners for this product? So if you can just draw the landscape broadly for this product over the next two years?
- Nilesh Gupta:** I think on India - on the injectable, I mean there's going to be many players. We'll have it in that first wave as well. The more interesting part to solve for in India is the oral product, and we're hoping to have that at the time of loss of exclusivity as well. We think that that will be the more important product to deliver on and that will come from an internal development.
- And then for other markets, we're obviously looking across, I mean Canada we talked about earlier. But Vinita, do you want to add for other?
- Vinita Gupta:** For the oral solid, which is an opportunity also in multiple markets, we have internal development. And for the injectable Semaglutide, we have partnerships in place. For a few markets, we have existing partnerships, others in the works. But we would expect the '27 calendar year to be in at least a handful of the open markets for Semaglutide.
- Saion Mukherjee:** And in terms of capacity, anything you can share? Your ability to service the markets? Have you invested in that from a formulation perspective?

- Vinita Gupta:** For the oral solid, definitely we have internal capacity, as well as injectable, although we have partnered with companies, we have the ability to double up with our Nagpur facility. But right now, we are counting on partners for the injectable.
- Saion Mukherjee:** And next one was on green propellant. You mentioned Vinita about that opportunity. So how should we think about it? When do we get more clarity on this? And how meaningful this opportunity you see at this point?
- Vinita Gupta:** So we expect the metered dose inhaler market will move materially, maybe starting in five years, but definitely over the 10 years into the green propellant products certainly with the moves that the major pharma companies have made like GSK, AstraZeneca, as well as Chiesi. From a European standpoint, we hope to be at the forefront as a material player on the respiratory front, with our Xopenex® brand as well as other MDIs to bring better propellant products to the market. So we have multiple products in development right now, not at the stage where we are filing in the next year but certainly year next, fiscal year '27, we should start to see product filings.
- Saion Mukherjee:** One more question regarding biosimilars. We sense that the investments slowed down in the recent past. Any fresh thoughts there? Are you planning to step up investments in biosimilars? Any view you have on that space and Lupin's participation?
- Vinita Gupta:** Actually, it's a promising trend on the biosimilars front in the US in particular in the last 12 months, both from a regulatory perspective with the FDA easing the requirements on interchangeability, you don't need to do additional studies for interchangeability anymore. And with the trend on private labels from the large PBMs like with Caremark and Humira, what they did with the Sandoz, the Cordavis label that converted the majority of the market from Humira to the biosimilar, that is a promising trend on the market front.
- In the past, as we looked at it, both from a development perspective, we saw the biosimilars were fairly onerous, capital intensive, and then from a go-to-market standpoint you needed commercial infrastructure and both seem to start easing up at this point. So it's a really positive trend. I mean we have a good number of products for the near term, so we continue to invest in those. As I mentioned, Ranibizumab was filed in EU this past quarter, will be filed in the US. So we have Pegfilgrastim that we still see as an opportunity, as we get the product approved. We have Ranibizumab, Aflibercept, and then Etanercept in '29 that comes into the market in the US where we should be one of three in the market and then we have other products like Certolizumab and Mepolizumab respiratory products as well that we are pursuing. So actually, it looks like the biosimilar market is starting to open up and, as it does, we'll continue to look at opportunities. As it opens up and on the one side the challenges come down, but the competition goes up. So our focus is very much going to be in limited competition products where we're going to be in the first wave, where we can be one of two, one of three. That is the kind of focus that we will have from a portfolio standpoint. So it will be a fairly selective number of products that we will pursue.

- Moderator:** The next question is from Shyam Srinivasan.
- Shyam Srinivasan:** On the European market, the kind of growth that we have seen about 20%. If you could kind of articulate what's driven that growth. I think you called out two products, but just want to understand the sustainability of the growth in the European market for the path ahead.
- Vinita Gupta:** So you know, respiratory portfolio has been a big contributor in the European growth, in particular in the UK as well as Germany, where we've continued to grow our market share with Luforbec[®]. And now with the Nalcrom[®] addition in Germany in particular that's helped us grow Germany, you know, the combination of Luforbec[®] as well as Nalcrom[®]. So respiratory portfolio has been a big contributor for the European growth and we expect, you know, to continue revenues at the current level. So, wherever we can, we will grow share. We are getting into new markets in Europe as well. Right now we are in 13 countries with Luforbec[®] but have the potential of launching in countries like Spain and others. So continue to make inroads there.
- Shyam Srinivasan:** And just a second question, going back to the question on tariffs. If you see, there's increasing risk that 10% import tariffs come on critical imports in the US and the critical imports do include pharmaceuticals at this point of time. So I'm just going to ask a hypothetical question. In case it gets announced as early as next Feb 18th Feb seems to be the date, what are the mitigation efforts in terms of do we have pricing power to increase that onto our customers or you think we are going to have to absorb it at the start and then negotiate? Because moving manufacturing and other stuff while we have capacity probably takes time. So I just want to understand the push and pulls around - I know it's a hypothetical question but seems - given what is happening on trade, a more likely one than not. So just want to see from a management preparedness in case such tariffs occur, what is the thought process?
- Vinita Gupta:** So we are looking at multiple different avenues there to look at the impact and how you mitigate it. But as an industry, we have all aligned on the fact that the industry has gone through a lot of pressures. Critical medicines, high-volume low-price medicines cannot bear additional costs. So with 70% of the products imported into the country on the generic front, 50% contribution overall generics from India, I mean one would expect prices would go up in case on critical medicines, in case, the tariffs are implemented.
- So again, I mean it's hypothetical but as an industry, we have everyone recognizes the impact that tariffs can have on the cost of goods and understands that it either leads to a cost increase for the market or you're going to see disruptions in the market.
- Ramesh Swaminathan:** And you are not reckoning the response to the Indian government also. They actually reduced tariff on certain rates on certain categories of goods and so on from America. So we don't know their response for this particular category also as yet.
- Moderator:** We'll take the next question from Vivek Agrawal from Citi.

- Vivek Agrawal:** So the question is related to Tolvaptan. Given that this is going to be an at risk launch and you have highlighted that this is going to be REMS product and conversion is expected to be slower. So what kind of the market share you are expecting during exclusivity? Is this going to be let's say around 15%, 20% or maybe higher like 30% - 40%. So any colour if you can provide that would be super helpful.
- Vinita Gupta:** We hope that it gets to the 30% - 40% level based on the partnerships we have established with the key channel partners on the product.
- Vivek Agrawal:** And a related question. Post 180 days exclusivity, right, how many players you are expecting in this particular product? Maybe two, three or many other?
- Vinita Gupta:** Yeah. We are expecting two, three additional players.
- Moderator:** We'll take the next question from Nitin Agarwal from Dam Capital.
- Nitin Agarwal:** Vinita, there has been a lot of general concern in the sector with respect to sector facing certain sort of US sales erosion in FY27 post-Revlimid® sales going away. While we don't have the Revlimid® challenges, we do have our set of large ticket products in FY26 like Tolvaptan, maybe Mirabegron as you mentioned continuing in FY26. So I mean as you see the business looking through a couple of years out in FY27, do you see a risk of growing or , not growing over the FY'26 base that you will end up creating?
- Vinita Gupta:** So we have a strong pipeline that we are pursuing. Some of these products that we are expecting maybe competition to come in, just gone by how long it has taken for us to get approval on products like say Spiriva. That took us five years to get FDA approval. One believes that it's going to take longer for competition also to get approved. So we do feel, with the pipeline that we have in place that we should be able to continue to drive growth in the US market despite pressures on products where you lose exclusivity.
- Nitin Agarwal:** So I mean if we are going to do double-digit growth all over in '27 or '26?
- Ramesh Swaminathan:** It depends on so many things really essentially. So we have a rich pipeline but as you say there are moving parts because of various things. But over the next five years, we are focusing on what we think would be the complex portfolio and that would help in kind of securing growth over the next four years, five years.
- Vinita Gupta:** We expect in fiscal year '26, the US should be at a USD billion plus and then look at how we can sustain the growth from there.
- Moderator:** We'll take the next question from Neha Manpuria.
- Neha Manpuria:** Quick question first on the capital allocation. If I were to you know ask for a rank order in terms of, you know, where we would pursue M&A, would it be India, Specialty, biosimilars How should I think about priorities for capital allocation for Lupin?
- Ramesh Swaminathan:** **You correctly pointed out**, the highest priority would obviously be India. There would of course be opportunities in generics up to a particular limit in

other parts, including America. And of course, we have a larger chunk reserved for specialty itself.

Neha Manpuria: And would you like to earmark a number as to what we would like to spend in, India or US generic in case of acquisitions?

Vinita Gupta: I think Ramesh meant to say, you know, India, Specialty and then generics, wherever we need it, in that order. With specialty and India being the major focus.

Neha Manpuria: We don't have like an earmark number as to this is what we would like to invest in, let's say, India, Specialty?

Vinita Gupta: No, it's based on the opportunity and what we see in terms of synergies as well as growth potential.

Ramesh Swaminathan: But having said that, we would be comfortable with a bite-size acquisition, USD 200 million to USD 250 million should be easy enough for us.

Neha Manpuria: In each of these areas?

Nilesh Gupta: Several of them.

Neha Manpuria: Second, I think in the past, we've talked about CDMO opportunity, you know, that we're probably exploring, you know, for growth beyond, FY27. Any update there? Have we looked at Capex? You know, what's the thought process on that?

Nilesh Gupta: So we've spun out Lupin Manufacturing Solutions and there's a whole team that's been put together for this as well. Efforts are on in all earnest now. They're actually putting the strategy together, which they'll have in place. So we'd hope to give some more flavor on this next quarter.

Neha Manpuria: And have you earmarked the Capex for this, Nilesh?

Nilesh Gupta: No, it'll come along with the strategy.

Operator: We'll take the next question from Harsh Bhatia.

Harsh Bhatia: Spiriva market share for FY25, our target was somewhere around 35% - 40%. In December, as for the presentation, it's around 30% - 31%. So what are the plans for Spiriva market share at this stage, including commercial versus Medicare and Medicaid channel?

Vinita Gupta: So the team has done a really good job in activating multiple areas from a conversion standpoint, but we're starting to see some impact already in January where TRx share has become high 30's has gone to 38% level and NRx is 40% plus. So you know the multiple efforts on from a co-pay standpoint to ease the burden on the patient to access into Medicare/Medicaid through contracting, plus other avenues are starting to show results. So we are hopeful that we sustain this level into the rest of the quarter and into the next fiscal year to get the overall market share to hopefully 40% plus.

Harsh Bhatia: Just one clarification on this incremental market share that is standing out, earlier mentioned that at a commercial level, you were already at 40% plus.

So this incremental market share is sort of coming from the non-commercial side of the business?

- Vinita Gupta:** That's right.
- Harsh Bhatia:** And this is sort of related to the out-of-pocket capping that the innovator had undertaken let's say a few months back. Does that sort of relate to that in any extent?
- Vinita Gupta:** No, maybe we can take this question offline but it's needless to say the efforts that the team has put in to drive conversion to our generic are starting to show. We'll have to still continue to monitor the trend to see if it is sustainable but it's looking good so far in January to February.
- Harsh Bhatia:** Very lastly on this USD 250 million run rate for the quarter for FY26, basically USD 1 billion number. What is the assumption for Mirabegron, if I may ask for this number?
- Vinita Gupta:** We assume that additional competition comes in, in the second half of the year. On Mirabegron, we've assumed that Albuterol faces competition or impact of competition that has already started. And we've assumed that Tolvaptan helps tremendously in the first half and injectables plus Tolvaptan in the second half.
- Moderator:** We'll take one last question from Tushar Manudhane.
- Tushar Manudhane:** Just continuing on R&D spend. While we have highlighted INR 1,750 crores to INR 1,800 crores for FY25., would you follow it for FY26 as well? On an absolute basis, how much R&D spend will be?
- Ramesh Swaminathan:** I would say, as an absolute there would be an increase but as a percentage of sales, it will perhaps be around the same levels. But given the focus that we have on more complex stuff and the like, this is inevitable.
- Tushar Manudhane:** So INR 1,800 crores to INR 1,900 crores safe to assume that much of spend to happen?
- Ramesh Swaminathan:** Yeah, that's a slight increase over that if necessary.
- Tushar Manudhane:** And just if you could share specifically for Canada Semaglutide, like market in terms of units, how big it could be?
- Ramesh Swaminathan:** We can take that offline, please.
- Moderator:** I now hand the conference over to the management for the closing remarks.
- Vinita Gupta:** Thank you. Hopefully, we have been able to answer all your questions. We'll be happy to take any that we have not been able to get to offline. There were a lot of questions on what is likely to happen in the US from a tariffs perspective. And as I mentioned, we hope that the industry efforts do pay off in terms of to ensure the sustainability of the US generic industry in the interest of patients as well as other stakeholders.
- From a Lupin standpoint, we are very pleased with how the company has performed this fiscal year and really excited with the potential in the near



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term with our major growth drivers, looking very clear from an approvability standpoint as well as market launch standpoint, and improving market conditions in new areas for Lupin like biosimilars.

We look forward to continue to execute on our strategic plan to drive growth across key major markets and evolve our business from generics into more branded and specialty on top of complex generics in the year ahead and certainly in the next couple of years.

So thank you again for your support and attention. We look forward to catching up with you at the end of this fiscal year in May, hopefully in person. Thank you again.

Moderator:

Thank you so much, ma'am. On behalf of Lupin Limited, that concludes this conference. Thank you for joining us. And you may now exit the webinar. Thank you.