



November 8, 2024



“Lupin Limited Q2 FY2025 Earnings Conference Call”

November 8, 2024

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**



November 8, 2024

Moderator:

Welcome to Lupin Limited Q2 FY25 Earnings Conference Call. Please note that all participants' lines will be in listen-only mode and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded. I now hand the conference over to the management. Thank you and over to you.

Vinita Gupta:

Good evening everyone. I hope all of you had a great Diwali. I'm very pleased to welcome you to our Q2 fiscal year '25 earnings call. I have with me our MD, Nilesh, our CFO, Ramesh and our Head of Investor Relations, Ravi here. 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 double-digit revenue growth, led by strong commercial execution in our key markets and also backed by new product launches. We are in particular pleased with our EBITDA performance with 510 basis points improvement year-over-year and 50 basis points improvement sequentially, despite higher investments in R&D.

We feel confident of maintaining our growth momentum in the coming quarters with EBITDA margins in the 22% to 23% range for the fiscal, based on our business momentum and continued focus on driving efficiencies.

Our US Business performance was strong this quarter with volume-led growth in in-line products, and strong performance in our respiratory portfolio, offsetting additional competition in products like Suprep® and Doxycycline.

With the recent successful launch of Mirabegron 50 milligram, and Pred Forte® with the CGT exclusivity, we feel confident of delivering close to double-digit growth in the US this fiscal.

Also we have continued 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. So far, we have evolved our business to 40% complex generics, and we have an exciting pipeline with more than 20 respiratory products, and 40 injectable products in development that we believe will enable us to continue to drive the shift to 50% plus in the next couple of years.

Coming to India, we reported strong growth of 19% year-over-year led by growth in our India formulations business and additional tenders in our Global



November 8, 2024

Institutional Business. Our India Formulations business recorded growth of 10.9%, 40% ahead of the market. For H1, our growth was 30% ahead of the market, so very strong momentum in India.

Volume growth in the quarter was a strong 3.5%. I'm happy to report that all our key therapy areas Cardiac, Respiratory, Diabetes and GI grew ahead of the market. I would like to specifically call out our Diabetes portfolio which was challenged in the past due to loss of exclusivities on brands. Our Diabetes business now, grew 19% year-over-year against the category growth of 9% in the quarter. We feel confident on continuing to deliver above market growth in our India Formulations business backed by a strong portfolio of innovative and in-licensed products, and extensive reach through our 10,000 people sales force.

Our non-US developed markets grew 20% year-over-year driven by strong growth in key markets like Canada, UK and Australia. Growth was contributed by both in-line products like Zaxine® in Canada, Luforbec® our Fostair® generic in the UK, as well as new product launches. We also witnessed healthy growth in our key Emerging markets like Mexico and South Africa during the quarter.

On R&D, as planned, R&D as a percentage of sales has increased to 8.2% during the quarter. We successfully completed Phase 3 for our Ranibizumab biosimilar this quarter which paves the way for us to file the product in the US and EU this year. We expect R&D to be around INR 1,800 crores for fiscal year '25 with an increasing percentage of complex generics as planned, primarily in the respiratory as well as injectables platforms.

From a compliance perspective, we have submitted our responses to the recent FDA audits at our Pune Biotech and Pithampur Unit-I facilities. We would like to reiterate that we are committed to ensure that all our sites are fully compliant with US FDA and other regulatory agencies around the world.

Before I hand it over to Ramesh, I would like to say that we remain very optimistic on our growth potential both in the short and medium term. Our strategic growth levers are well defined and backed by an exciting pipeline of products in our chosen markets and key therapy areas. We are committed to driving efficiency measures while leveraging our investments across all major geographies. We are confident on building on our momentum both in terms of top-line and profitability going ahead. With this, I will hand it over to Ramesh.

Ramesh Swaminathan:

Thank you, Vinita. Friends, I welcome you all to our Q2 FY25 earnings call. I am happy to announce that we have delivered another quarter of consistent double digit revenue growth across most of our geographies. We have also

increased our EBITDA margins despite an almost 190bps QoQ increase in our R&D spend.

Diving into the numbers.

Sales

Sales for Q2 FY25 came in at INR 5,497 crores as compared to INR 4,939 crores in Q2 last year, a growth of 11.3% YoY. On H1 basis, sales came in at INR 11,011 crores vs INR 9,681 crores last year, growth of 13.7% YoY.

We have registered robust growth across most of our key geographies. India business has grown 19% YoY, North America has grown 6% YoY, EMEA grew 20% YoY, Growth markets grew by 12% YoY whilst API grew 10% YoY.

The US Business

In the quarter the US business recorded sales of USD 220 mn, a growth of 3% YoY on constant currency basis. As Vinita mentioned, volume growth in our base products, and increased sales of respiratory products were offset by increased competition in products like Suprep[®] and Doxycycline and low single digit price declines. We also had impact of high channel inventory for some of our new product launches which will get normalized going ahead. Based on our visibility of new product launches like Mirabegron 50mg and Pred Forte[®] amongst others, we are confident of meeting our guidance of close to double digit revenue growth in the US for this fiscal. We also continue to execute on our strategy to improve our profitability in this segment, with another quarter of high profitability from this business. On a long-term basis, we remain confident of consistent delivery of profitable growth through an increasing share of complex products in our portfolio.

India Region

Coming to India, the India business grew by 18.8% year-on-year during the quarter. With this, the prescription business has grown 10.9% year-on-year, outperforming IPM growth by 1.4x during the quarter.

Even on H1 basis, the prescription business has grown at 10.8%, handsomely outperforming IPM by 1.3x. Our chronic segment has grown 13.5% year-on-year during the quarter, against an IPM growth of 9.7%. If you look at our top three segments of Cardiology, Diabetes and Respiratory, we have handsomely outperformed their individual category growths within the IPM.

I would also like to mention that as per IQVIA, Lupin is ranked number three in so far as new product introductions are concerned. The share of in-licensed products is around 12% as compared to 15% last year, which also has a positive impact on our profitability going ahead.

I would like to mention that in our India region, outside the India prescription business, our adjacencies and domestic part of our Global Institutional Business have also performed well in this quarter, with revenues of INR 208 crores versus INR 66 crores in Q2 last year.

In so far as other businesses, revenues in our ex-India, ex-North America formulations business which includes EMEA, ROW and Growth markets have increased 10% year-on-year to INR 1,222 crores, and now constitute 22% of our sales.

EMEA

In so far as EMEA is concerned which constitutes our EU region and South African business, this registered strong growth of 20% year-on-year during the quarter. This has been driven by healthy growth in EU markets like UK from Luforbec® and other products.

Growth Markets

Our Growth markets include APAC and LATAM regions have grown 12% year-on-year during the period. The APAC market grew by 10% year-on-year during the quarter led by strong growth in markets like Australia. LATAM market grew 14% year-on-year in the quarter due to strong growth witnessed in Mexico.

Profit and Loss

Coming to the P&L aspects, Other operating income of INR 176 crores has increased by INR 76 crores this quarter. This mainly due to PLI and other export benefits during the quarter.

Gross Margins

Coming to the profitability, Q2 FY25 gross margins were 69.3% up from 68.4% in Q1, and 65.5% recorded in Q2 last year. The improvement is driven by multiple factors, which includes, product mix, tailwinds on input costs, lower share of in-licensed products, increased volumes, and various cost improvement and efficiencies which we have undertaken over the past several quarters. Barring any unforeseen circumstances in terms of our geopolitical uncertainties in the Middle East are concerned, we feel confident of maintaining a gross margin around these levels going ahead.

Employee Benefit Expenses

At INR 1,007 crores increased 17% year-on-year from INR 861 crores in Q2 FY24, and INR 971 crores in Q1 FY25, translating to 18.3% of sales vis-a-vis 17.4% last year and 17.6% in Q1 FY25. This change is largely attributable to higher cost, attributable to regular annual increments and business growth during the period.

Manufacturing and Other Expenses

Q2 FY25 manufacturing other expenses came in at INR 1,667 crores which translates to approximately 30.3% of sales as compared to 31.4% of sales in Q2 last year, and 29% of sales in Q1 FY25, reflecting a growth of 7%. The expenses are mainly higher due to higher R&D costs and some extraordinary provisioning leading to some disputes.

Research and Development

R&D is at INR 448 crores, which is 8.2% of sales in Q2 FY25 as compared to INR 350 crores at 6.3% of sales in Q1 FY25. Almost two-thirds of our R&D is directed towards complex portfolio. For the full year, R&D is expected to be around INR 1,800 crores.

EBITDA

Excluding Forex and other income, EBITDA was INR 1,308 crores vis-a-vis INR 923 crores, an increase of 42% year-on-year with margins of 23.8%, vis-a-vis 18.7% last year in the same period. On a quarter-on-quarter basis, margins have expanded by 50 basis points. This margin expansion is on the background of higher R&D spends, which have increased by 190 basis points quarter-on-quarter during this period. If you look at our EBITDA margin profile, we made improvements across all our key segments. Our gross margins are higher by almost 1% quarter-on-quarter, and there has been increase in the operating income and we benefited from cost savings all over.

We also made additional provisions of INR 58 crores for an ongoing dispute. Putting this all together we believe that we should be able to deliver EBITDA margins in the range of 22% to 23% for the remaining fiscal.

Tax

On the tax line, our ETR is 18.7% during H1 FY25. For the full year, we expect it to be around 20% to 21%.

Balance Sheet

In so far as the balance sheet is concerned, operating working capital was about INR 6,562 crores as of 30th September against INR 5,691 crores in March '24, which translates to 107 days of net working capital against 105 days as of 31st March, and net debt is about INR 274 crores against INR 477 crores in March again.

Whilst we focus on increased cash generation from our business, we'd like to highlight that we continue to actively explore strategic allocation of our capital to address the long-term growth vision of the company.

ESG

On the ESG front, Lupin has achieved S&P Global ESG score of 76 in the recent bout of admissions from the concerned body, the industry average being just about 30 in the pharmaceutical sector. Our S&P score reaffirms our commitment to prioritizing sustainability and creating impact on sustainable healthcare solutions that benefit patients and communities worldwide.

Seven of our Indian manufacturing sites got successfully reassessed for human rights assessment, with five sites retaining Platinum rating and two others moving from Gold to Platinum. With this we open the floor for discussions.

Moderator:

Thank you so much, sir. We will now begin the question-and-answer session. Please raise your hands from the participant tab on the screen to ask questions. We will wait for 30 seconds for the queue to assemble.

We'll take the first question from Saion Mukherjee.

Saion Mukherjee:

So my first question, Vinita, is that for future launches you talked about injectable Glucagon and Dalbavancin. Can you just talk to us about the visibility of these launches and what kind of upside you are expecting from these products?

Vinita Gupta:

Injectables right now are a very small part of our portfolio so were looking forward to these approvals. We expect Glucagon and Dalbavancin in the next couple of quarters. One may be in Q4 and I think one might slip into Q1 of next year. But over the next couple of quarters we should be seeing these approvals.

Plus, Risperidone we expect in the next fiscal year, and potentially also Liraglutide - Victoza® we expect in the next fiscal year. So we really see the injectables portfolio building very nicely starting the end of this fiscal year through the next fiscal year on top of our respiratory and other exclusive orals.



November 8, 2024

- Saion Mukherjee:** Particularly on Dalbavancin, is that an exclusive product for you? How are you expecting competitive intensity here?
- Vinita Gupta:** We see a couple of competitors, but still limited in number compared to other injectables.
- Saion Mukherjee:** The second question I have was on the India and Emerging market opportunity on the GLP-1 space. So if you can take us through what you're thinking about India and Other Emerging markets, what are your preparedness and how you're seeing this opportunity?
- Nilesh Gupta:** It's essential that we bring this as a leading Cardio-Metabolic company, we're ranked number two. Obviously, we want to bring these products to the Indian market as well. We aim to be in that first wave of generics coming into the market. So likely in 2026, we would hope to launch the first of several. I think everybody is chasing a whole bunch of products at this point of time. So, I think there is importance to bring this sooner rather than later. But I think, short answer, 2026 we hope to launch the first of these.
- Vinita Gupta:** And I'd just add to that also other Emerging markets we have positioned ourselves to either live partner the product or internal development to contribute to the market when it opens.
- Moderator:** We take the next question from Neha Manpuria.
- Neha Manpuria:** Ramesh, in your opening remarks, you gave us several reasons for the gross margin improvement that we have seen. And I think that you mentioned you expect the gross margins to maintain at these levels. So, would that be in the first half range that you're seeing in the 69% to 70% or the quarter, just wanted to get a sense on that?
- Ramesh Swaminathan:** 68% to 69% is a good range to kind of sustain for the future.
- Neha Manpuria:** And what according to you has been the biggest driver for the margin improvement that we have seen in the first half? Is it product mix? Is it the input cost? And if you were to pin down, the top two areas where you've seen the most improvement?
- Ramesh Swaminathan:** I would actually say three things. One is of course the sales mix, Mirabegron of course, contributed there. The second is essentially the procurement costs, which is also coming down, and we expect that to continue to go down in the quarters to come. And the third, of course, there are a lot of operational efficiencies that have kicked in over time. For starters, the gross margins line itself, we do have firstly, alternate vendor development that we have done for key products and key materials.
- And the second part, in so far as for example we have air freighting which has been reduced and we are now more into the ocean freighting mode. So all of these kind of efficiencies have helped in kind of bringing up the margins to the levels that it has come to.



November 8, 2024

- Neha Manpuria:** And I think Vinita also mentioned that we are seeing improving profitability in the US, is it fair to assume that the US margins now are higher than our corporate margins?
- Ramesh Swaminathan:** Yes, absolutely.
- Neha Manpuria:** And last, what was the number for the Global Tender business in the India sale this quarter?
- Nilesh D Gupta:** About INR 150 crores.
- Moderator:** The next question is from Bino Pathiparampil.
- Bino Pathiparampil:** Just wanted to follow-up on your GLP strategy. Globally you said '26 it starts, and could you give us some sense of when the markets open up globally, not just the US for the Semaglutides, Tirzepatides, et cetera, especially semi-regulated markets et cetera?
- Vinita Gupta:** So more of the regulated markets are actually patented till later. The loss of exclusivity is expected I think in 2030 for the developed markets with the exception of Canada. But India, South Africa, Latin America, Philippines, some parts of Eastern Europe, those are the markets that are available for us to launch in '26.
- Bino Pathiparampil:** And you have a strategy in place to be in the first wave of launches in these countries?
- Vinita Gupta:** So, we have definitely positioned ourselves for India, and South Africa we have a license. So, a combination of our internal development as well as in-licensing, we have positioned ourselves in all the key markets where we can really participate in the category.
- Bino Pathiparampil:** Second question about your new initiatives on the CDMO space. You have worked earlier in that space a bit with some innovators. Now you have set up a subsidiary, are you trying to refocus there especially in the context of Biosecure Act et cetera?
- Nilesh Gupta:** I mean that's exactly why we created Lupin Manufacturing Solutions. Obviously, it's early days, we're putting the team together. I think we've got almost all the entire structure that will fall in place between this quarter and the next quarter. And then obviously, I think we need to put our head down and give it a year or two years of good work to be able to talk about this. But we're very optimistic about what we should be able to deliver out of that. I think there's some very positive trends towards India, and I think that opens up the headroom for companies like us to be able to capitalize on this. Very excited with this venture.
- Bino Pathiparampil:** But what would be your value proposition versus pure CDMO companies?
- Nilesh Gupta:** It is going to be a pure CDMO company in that, I mean it's a separate company and everything is structured as such in that. I think if you look at just the variety of technologies that we would have; if you see the understanding of regulated markets, I mean we're not unique in this. There's obviously a few other companies that would be able to do this even out of India. But I mean,



November 8, 2024

we have the ability to play at scale in this space. We believe we have a right to win. I think we understand chemistry, we understand technology, we've done this for years, we understand regulations, we understand quality and we are getting the right kind of commercial capabilities in place as well, which is key. Some of the other disciplines like project management and the like are different, and we are obviously building and acquiring capability. But the intent is to play this as a pure CDMO player in that part.

Bino Pathiparampil:

One last question to Vinita. In the US quarter-on-quarter revenue has come down a little bit and this is despite Mirabegron 50 mg being launched almost a month before the end of the quarter. So what has primarily led to that Q-o-Q decline in revenue? I assume that Spiriva® has continued to do well from your comments. Is it some fluctuation in the base business or some Albuterol hit?

Vinita Gupta:

Actually the base business has been fairly strong. I mean there's been some phasing on Mirabegron because we had the inventory load in the first quarter for the 25 milligram and for the 50 milligram it was more substitution. So it was not as much of an inventory load, but you'll see that normalize in the second half of the year. And then it was really additional competition in products like Suprep® and Doxycycline. Like I mentioned, we had some erosion there. But the base business, respiratory portfolio as well as Mirabegron from a share perspective has continued to build in Q2, and it's just the phasing of the inventory load on the Mirabegron also that has a little bit of impact between the two quarters.

Moderator:

We'll take the next question from Anubhav Agarwal.

Anubhav Agarwal:

I just want to get some more clarity on the specialty business where you had a new president as well last month. So, what areas you're trying to focus here? What will be risk appetite? How do you want to build it? Earlier the company was focused more on the women's specialty area. How are you thinking about it here?

Vinita Gupta:

So, our focus is on the two therapy areas where we have a presence. I mean right now we have a small presence on the respiratory front in the US with Xopenex®. And in Europe, our franchise is a branded generic franchise so that is one, and two neurology, again where we have a presence with NaMuscla® in Europe. We are looking to expand that into the larger indication. Right now it's NDM and we have started to conduct a study for DM for global commercialization of NaMuscla® in particular Europe and the U.S. The focus is the two therapy areas that we are already present in. And very excited to really have Klaus on board. He brings in tremendous experience and in particular the two areas of our interest, respiratory as well as neurology. But as an organization, we will build this out in a cautious manner.

As we have stated, I think in past interactions as well, we would like to really build with accretive assets in the near term as we continue to really drive our EBITDA margin expansion from the 23% level to the mid-20s and above over the next five years.



November 8, 2024

Anubhav Agarwal: So just one sub-part of clarity on this question. So do you see yourself or Lupin basically acquiring mid-size assets here, USD 100 million to USD 200 million kind of assets, bouquet of about three - four products over a period of three, five years. Or is that the way when you say cautiously build this up?

Vinita Gupta: We'll look at medium sized assets that can really help us build the business as well as our own organic portfolio. With the capabilities we have on the respiratory front, we're building a pipeline of green propellant products where we hope to be in the first wave along with the other brand companies. We have our own brand in Xopenex®, so we have that opportunity. So combination of mid-size acquisition opportunities that make sense for us as well as organic build with a pipeline.

Anubhav Agarwal: So then on the US Generic business, on Generic Spiriva®. I'm just trying to understand the market share is largely around 30%. So I'm assuming there is no production constraint. This is just your reading of the market. You're trying to maximize your potential here. Should we assume that till the time the next player comes in, which could be fiscal '27 or thereabout, would you largely remain around 30% or what would trigger this 30% to go, 35% or 40%?

Vinita Gupta: Right now, we have kind of stabilized at that 30% level and the brand has held on to 70% share. I mean when we look at the different channels in the marketplace, in the commercial space we have more than 50% share. But in the Medicare - Medicaid space, our market share is lower. That's what driving it down to the 30% level.

So we have efforts ongoing to expand the awareness and try to help conversion in the Medicare - Medicaid business, and hopefully can drive that over the next couple of quarters to the mid-30s. But right now we have stabilized at a 30% level.

Anubhav Agarwal: And in the commercial space you think 50% is an optimum level or that could be 60% - 70% as well.

Vinita Gupta: We are already above that 50% level in commercial.

Anubhav Agarwal: On Mirabegron, I saw that Astellas got expedited review approval from the Court of Appeals. Not the outcome, but the total process of litigation, can we assume that this gets done either ways in couple of quarters from here or could this be extended to let's say a year from here?

Vinita Gupta: It's really hard to predict that, at this point the case was remanded back to the district court and I'm sure that the brand, whatever the outcome is going to likely challenge us if it's not in their favour. So, it's hard to really predict. But we were pleased that it was remanded to the district court that already ruled in the favour of generics.

Anubhav Agarwal: So, clarity was on the expedited review that Astellas just got it in starting October a month back. Does that have an implication on the timing of the case?

- Nilesh Gupta:** I mean that's one part of multiple cases which are going on in Mirabegron. So this does drag out for well over the next few quarters any which way.
- Moderator:** We'll take the next question from Girish Bakhru.
- Girish Bakhru:** Just going back to Glucagon. I mean you had commented for maybe Q4 launch. Just wanted to know is this a kit presentation or a vial presentation?
- Vinita Gupta:** It's injectable. It's a vial in a kit for what I think. But we can get back.
- Nilesh Gupta:** I believe we did the kit, but we'll just check.
- Girish Bakhru:** And I mean I'm probably also understanding the market is shifting here, because I think the use of the product is now shifting mostly to diagnostic chains in the US, that's why the vial presentation is probably getting bigger. But I mean would the market size have become different as per your understanding?
- Vinita Gupta:** We don't expect any material shift in the market right now. Majority of the market is with Amphastar. And we expect to be one of a few competitors. So it's an attractive opportunity for us, the way we're looking at it. We haven't really come across a material market shift here.
- Girish Bakhru:** Because Amphastar is only selling kits actually. And vial market is what is actually I read that is growing. That's why I was confused, what presentation actually would one focus on?
- Vinita Gupta:** Why don't we get back to you about that?
- Girish Bakhru:** And just on the Risperidone, I mean, we have one generic which is already approved. We have a 505(b)(2) I think already approved. I'm not sure if it's too early to call or whether the shift from brand to these newer players is happening already in the market at an expected pace. But is this going to be a product which is very difficult to shift the prescriptions from the brand to generic?
- Vinita Gupta:** So, I understand that the 505(b)(2) has been slow uptick at least in the last couple of quarters. And so we still expect in the near-term for the primary product to which we have a generic to be a material opportunity for us.
- Girish Bakhru:** Teva is already in the market, I'm guessing and their also numbers are pretty low right now.
- Vinita Gupta:** Yes, but Teva also has the 505(b)(2).
- Vinita Gupta:** So they have both the 505(b)(2) as well as the Generic. We don't know how they are positioning each.
- Moderator:** We'll take the next question from Damayanti Kerai.
- Damayanti Kerai:** My first question is clarification on other operating income. So Ramesh, did you mention INR 76 Crore of PLI and other export benefit or number is something different?

- Ramesh Swaminathan:** Yes, that's what I meant. There's a higher quantum, increased by INR 76 crore during the quarter.
- Damayanti Kerai:** Increase from which level? Just, just you can just quantify for the second quarter, please. Like how much is that?
- Ramesh Swaminathan:** Yes, just INR 165 crores in this quarter, and INR 86 crores in the previous quarter.
- Damayanti Kerai:** My second question is for Vinita. So can you also update us on your respiratory pipeline in terms of which key assets are due for filing or approval in say next two to three years?
- Vinita Gupta:** So, we have a few nasal sprays that should get approved in the next two years. We have Dulera® that we are actually in the process of doing additional studies to be able to respond to the agency. We hope to be able to respond to the agency in the next fiscal year. So that should be hopefully, fiscal year '27- '28 opportunity for us. And then in the current fiscal year, we have multiple products in development. But the major ones, both the Respimat® and Ellipta® products, we have planned exhibit batches before the end of this fiscal year. So have made significant progress there as well.
- Damayanti Kerai:** And most likely these Respimat® and Ellipta® products are say '27 and beyond opportunities, or it could be earlier?
- Vinita Gupta:** No, it won't be earlier because we'll have to certify against the patents as well.
- Damayanti Kerai:** My last question is on GLP opportunities which you mentioned. So, just want to understand in terms of capabilities which are your key areas of strength and will you be manufacturing it in-house to supply to global market? Like developed markets will come later but once you start in '26 so manufacturing will be in-house or it will be done through CMOs?
- Nilesh Gupta:** So, for products like Semaglutide, obviously we would do it in-house, because we obviously have both oral and injectable capability. For other products I think it all depends. It depends on the alliance that we would try to seek and the like. So, I mean everybody is chasing multiple products at this point of time. Some of them may be just simple in- licensing, others are where we could manufacture, we would love to be able to manufacture as well. I think that strategy will really play out in the next year and we'll have more clarity at that time.
- Damayanti Kerai:** So, it will be mix between in house and maybe depending on market opportunity. Right?
- Nilesh Gupta:** Yes.
- Moderator:** We'll take the next question from Kunal Randeria.
- Kunal Randeria:** My question around Liraglutide, given that the drug is not as efficacious as Semaglutide, has higher dosing frequency and now there is already one AG in the market with few more lining up. Just wondering how do you see this market shaping up in future?



November 8, 2024

- Vinita Gupta:** Well, Semaglutide and the follow on products obviously is where the market has moved to. Liraglutide is still a substantial market, both Victoza® and Saxenda®. So we still look at it as USD 1 billion dollar plus market with hopefully staggered entry of players. So we're looking forward to the approval.
- Kunal Randeria:** So do you think there'll be a sharp price erosion and then at the same time the volumes could go up?
- Vinita Gupta:** I mean that could be a scenario. I mean it's hard to predict. But we are chasing the applications with the FDA, to be able to hopefully get into the market next year.
- Kunal Randeria:** My second question is around Albuterol. Now you did make some reference to your share being low in the Medicare setting. I guess the brand share is very high over there.
- Vinita Gupta:** I was talking about Spiriva.
- Kunal Randeria:** Okay, sorry.
- Vinita Gupta:** It was in reference to Tiotropium, not Albuterol.
- Kunal Randeria:** Let me ask on Albuterol then. But even in Albuterol, in the Medicare setting the share of the brand is pretty high. So how do you see this Medicare USD 2 per month out of pocket thing playing out for generic companies like yours?
- Vinita Gupta:** We really don't see any potential impact of the USD 2 program because it's more to cover the out of pocket costs for patients. So it's the plan coverage and if anything, I believe that it can potentially expand usage of the drug, if the product is available at a low out of pocket cost to patients. As far as Albuterol goes, the substitution in Albuterol is pretty strong from a generic perspective. As you know, even the brand companies have launched authorized generics on the product. So, a good 80%plus of the market is really with authorized generics and generics.
- Kunal Randeria:** Even in the Medicare setting?
- Vinita Gupta:** Yes.
- Moderator:** We'll take the next question from Shashank Krishnakumar.
- Shashank Krishnakumar:** My first question was on the margin front. So given the trajectory of gross margins and other expenses, is there any rating in terms of the medium-term margin aspirations or the medium-term margins that we're guiding to? I think I heard 22% to 23% this year. Beyond FY25 how are we looking at margins?
- Ramesh Swaminathan:** There are two aspects to this. Obviously, we believe that our core should be in the range of about 23% - 25% and that is something that we would get to in the medium term. So, there is this aspect of adjacencies also, which actually some of these are still loss-making in the current context which should obviously spin on their own axis in the next couple of years because we intend spinning it off and bringing in private equity to participate. , And they would of course have grown and become more profitable as well. If you were to

knock out the impact of the adjacencies, you would actually have an EBITDA margin higher by about 0.8% during this particular quarter itself. It's coming down for sure vis – a -vis the previous quarter for example, and steadily becoming more profitable. And that could really alter in the next couple of years.

Shashank Krishnakumar: Secondly, just wanted to check if this quarter so far in Albuterol, have you seen any impact of Amphastar's launch? Though the company has been saying that they themselves don't expect meaningful contribution this quarter. But have you seen any impact so far?

Vinita Gupta: No, not in this past quarter.

Ramesh Swaminathan: I also wanted to clarify something, there's so much of questions around the PLI and the like as well. The scheme provides for INR 1,000 crores over a period of five years, as all of us know this, so that actually roughly means about INR 200 crores. But it also actually provides for an exception, where you could actually take a quantum a little more during the course of one particular year. It's an exception really to the framework. And we've taken advantage of this, this year because the fact that there's a surge in terms of exports and the like. And obviously, money into the kitty much faster is always better for us. And that's the reason why you would find a higher quantum of PLI money is coming in this year, but doesn't necessarily mean it's going to be the same quantum spread over the next several years.

Moderator: We'll take the next question from Kunal Dhamesha.

Kunal Dhamesha: The provision of INR 58 crores, what is it related to and how should we think about it? Is there more liability that can come for us?

Ramesh Swaminathan: This is a measure of abundant caution so to speak. As with every company, we also have our share of litigation, disputes and the like as well. So we just thought in the goodness and the fitness of things that you would provide for something and that's what it is. And it's just that it's an abundant caution, you don't need to read too much into it. It's not something it should repeat unless things go horribly wrong or something which we don't think it'll ever materialized that way.

Kunal Dhamesha: Which business segment does it belong to like geographically?

Ramesh Swaminathan: Well, it's basically a general provision, I would say attributable to certain disputes.

Kunal Dhamesha: And then there is also, when I look at our current provisions there is almost cash outflow of INR 400 crores between March and here. So what does that refer to?

Ramesh Swaminathan: It's basically, we paid out our dividends and the like. So, from that perspective you would actually see, it was a cash surplus company towards the end of last quarter. But then there was of course the slight increase in working capital, it increased by about three days, four days. And then it's of course the dividends outflow, which has caused this cash outflow.

- Kunal Dhamesha:** And on India business, out of our total revenue this quarter, if you can help us understand the three parts to it. I think one is prescription business, another is a tender business and then adjacencies like diagnostics. So can you provide colour on what is the contribution from each?
- Ramesh Swaminathan:** Well, we don't go into segment wise and I wouldn't like to do that at all. But I just did tell you about the fact that adjacencies are still loss making and this is essentially the diagnostics business and digital, and there's of course some parts of OTC and so on. But that all of this put together actually impacted the EBITDA margins by about 0.8%. The tender business of course is profitable. It gets included because it actually emanates from this particular geography, and that actually increases overall quantum in this quarter to growth to about 18%.
- Kunal Dhamesha:** And this tender business, would it be meaningfully lower gross margin business than our India business or would it be in line? How to think about it?
- Ramesh Swaminathan:** Well, we are not actually revealing geography wise margins. So that question might not be relevant in that sense. But as with every tender business, you would expect in fact the gross margins to be lower than the retail business in a general sense.
- Nilesh Gupta:** I mean just to give nature; I think 90% plus is in any case the Rx business that we're talking about here.
- Ramesh Swaminathan:** Absolutely.
- Kunal Dhamesha:** But then I don't understand. The total India business growth is 19% and we are saying Rx business growth is 11%. Then a huge chunk is coming from tender. Isn't the way to understand it or what am I missing here?
- Ramesh Swaminathan:** Your question related to a sales quantum as well as the profits. We are not talking about segmental profits at all out here. 11% increase in India region sales for sure. There's of course the OTC and diagnostics business which have also gone up, over the quarters. And there's, of course, the tender business which has also been represented in the overall figure of this 18% - 19% growth.
- Nilesh Gupta:** So in the year-on-year the number was very low last year and the number is a substantial increase. We already talked about the Global Institutional business being INR 150 crores in the quarter.
- Kunal Dhamesha:** And entire of that flows into India business as we reported?
- Nilesh Gupta:** A good portion of that for this quarter reported into the India business. Sometimes it's export, sometimes it's domestic. Actually our press release in any case would give you the India region business as well as the India region formulation business, so we do give that split.
- Moderator:** We'll take a few seconds before taking additional questions, and wait for the queue to assemble.
- We will take the next question from Alok Dalal.



November 8, 2024

- Alok Dalal:** **So, Vinita** just to clarify, Ranibizumab filing will be end 2024, is that correct?
- Vinita Gupta:** Yes, this fiscal year.
- Alok Dalal:** And do you expect this to be a first wave launch? Lupin in the first wave?
- Vinita Gupta:** No. There are already products ahead of us. But we expect it to be a decent sized product given the fact that it's an ophthalmic product and we already have relationships with some of the ophthalmic distributors.
- Alok Dalal:** And apart from this product which are the other biosimilars in the pipeline and launch timelines for those?
- Vinita Gupta:** So, we are hoping that Pegfilgrastim is going to be our first one. And we are waiting for FDA approval for the product and have the ability of launching it as well, hopefully in the next 12 months', subject to FDA approval and clearance of the Pune site. Ranibizumab would be the second one. Aflibercept also is progressing well in development, so building on the ophthalmic franchise. And then we have couple of partnered products, Denosumab in Japan with a partner. We don't have plans to bring it into the other markets unless we find a partner. And then Etanercept in the US in '29. And then we have a couple of products that are earlier stage, especially the respiratory biologic like Mepolizumab and Benralizumab, earlier stage in development.
- Alok Dalal:** So, it appears that in each therapy area there is one or two products. With this kind of portfolio then will you have your own field force in the US, or will this be a partnered field force?
- Vinita Gupta:** So, we have a cautious approach on biosimilars. We don't plan to really build market presence for each therapy area. So, we intend to partner where it makes sense. And if we have the ability to leverage our infrastructure, if there is a synergy with the rest of our business, then we will commercialize ourselves.
- Moderator:** We'll take the next question from Saion Mukherjee.
- Saion Mukherjee:** **Vinita**, On NaMuscla[®] and generic Fostair[®], what is the headroom to grow this business in Europe? And on NaMuscla[®], you mentioned about the new indication for US and Europe. If you can talk about the timeline on that indication and what's the market size one can expect?
- Vinita Gupta:** So, we are really excited about the potential of NaMuscla[®] and the DM indication, DM1 and DM2. We have started the study already, and also got FDA feedback on the DM study. And believe that we should be in a position to file to the US in '26. So it will take us through next calendar year into '26. But the potential we see is sizable. In Europe, the potential of the DM indication is multiple times the NDM. We think it could be USD 100 million product in Europe, and then in the US based on pricing, it can be well beyond that. So, in Europe, likely we will launch first. But, the team is in the process of putting the plans together, especially with the addition of Klaus now,

making sure we can leverage the opportunity across all the developed markets on a timely basis.

Saion Mukherjee: So fiscal '27 is what you're indicating as filing and then in fiscal '28, possible commercialization in the US, is that the right understanding?

Vinita Gupta: That's right.

Saion Mukherjee: Okay, and do you have for this new DM indication any clinical data with you which suggests commercial success of this product, or we have to wait and see for the Phase-III data to come before you kind of get the confidence of having this as commercial success?

Vinita Gupta: Well, so, right from the start, when we embarked on this product, we knew that the product works for NDM and DM. We know that clinicians have been using it off-label and that's why we thought that it was a low-risk study to pursue. And likewise for the DM indication also, while the data will have to prove it obviously and make it to the label for us to be able to commercialize it effectively, we have a high degree of confidence that the product works. There's nothing else available for the indication. So, the physicians are very enthusiastic about seeing the product make it through clinical development to the market.

Saion Mukherjee: And any comment on generic Fostair[®] as to how much more opportunity is there for Europe?

Vinita Gupta: It's been a substantial growth driver for our European business and continues. As we look at the next fiscal year, Luforbec[®] continues to be a major product for us in Europe. So far, we have got into some of the major markets. We have not entered Spain as of yet. We have a presence across 11 countries at present. So, continue to expand geographically as well in Europe over the next year or two.

Saion Mukherjee: And in UK or some of the big markets, can you share market share?

Vinita Gupta: Why don't we get back to you? We are still the market leader apart from the brand and it's been a big growth driver for us in UK in particular.

Saion Mukherjee: Ramesh, one question on the employee cost. We have seen around 15% to 17% increase in the employee cost, which seems to be on a higher side. So if you can give some colour as to why the level of increase is this high, is there some new expansion that is driving it? If you can give more details on this?

Ramesh Swaminathan There is of course this complement of people who have been added during the course of this year, this quarter. And there is of course another in terms of the ESOPs. The share price has been going up and when we compensate people in terms of ESOPs, there is a charge to the Profit or Loss to that extent and that's being brought in here. And the third, of course, is the normal increments that you pay to people and stuff like that.

Saion Mukherjee: And just one last question, if we can ask on the tender business. So it seems for the last two quarters, this was at a higher level. So how should we think about the next two quarters? And maybe even in FY26?



November 8, 2024

- Ramesh Swaminathan** By its very nature, it is always going to be sporadic, essentially because there is some inconsistency. The overall business that you're competing in that is about USD 650 million across the world. But the timing of that is always very difficult to ascertain. For example, these tenders in India are delayed for a couple of years and the like. And then they brought the Latent TB along with in fact, the Global Fund. From that perspective, it's something which you can't really predict, but it's a market which is about USD 650 million, and we obviously are very competitive in that market.
- Nilesh Gupta:** You might see some lumpiness, but I think we'll largely be at this level. I think it's going to be a good year for that business.
- Moderator:** We'll take the next question from Tushar Manudhane.
- Tushar Manudhane:** So just on the GLP-1 opportunity as far as Emerging markets are concerned, in terms of the value chain, where is the key hurdle? Is it going to be the marketing or is it going to be the manufacturing? Like right from end-to-end manufacturing. If you could share your thoughts here?
- Nilesh Gupta:** I think in India it's about the commercial excellence. So it is going to be about that. And that's the reason why we're not that hung up that we have to manufacture this or the like. I think obviously when we do this for developed markets, we are going to want to control more of the value chain. So obviously, manufacturing, even the R&D, all of that would be done as well. But I think where we have branded generic markets there, it's more access to the product than anything else, which is important. And in other markets we would obviously do a more holistic play.
- Tushar Manudhane:** And given the kind of the business which let's say the innovator companies are making on this product, despite that the manufacturing won't be the constraint for the Emerging markets. Is that the right understanding?
- Nilesh Gupta:** Not for India for example. Right. I mean, I think the crown jewel in all of this is going to be the India conversation and I think in India it's going to be about commercial excellence.
- Vinita Gupta:** Besides, we have looked at our manufacturing capacity and if you launched in every market that opens up in '26 we are still able to manufacture internally if it came to that.
- Tushar Manudhane:** And secondly on Dalbavancin, what will be the market size?
- Vinita Gupta:** I don't have it off the top of my head.
- Nilesh Gupta:** We can get back to you.
- Moderator:** We'll take one last question from Shyam Shrinivasan.
- Shyam Shrinivasan:** Just the first one on the trajectory for the US business. It's been kind of range bound with the exception of say Q1. So just want to understand how should we look at the second half?
- Vinita Gupta:** I think like we said, we should be able to increase closer to the USD 230 million plus. Again, depending on the pressures that we see on some of the key

products. But overall inching up to over USD 230 million and likely the second half enabling us to close at a double-digit growth level for the year. And as we get into next year, first quarter we should have the impact of Tolvaptan plus the injectable products that we hope to get approved by the end of this fiscal year, early next year as well as others that we have on our plan. So we expect to get to that USD 250 million level through the next year to be able to be at the USD 1 billion plus next year.

Shyam Shrinivasan: And would that entail a much better margin profile for us in terms of the US or maybe what is the current US margins closer to corporate average or you think once we reach the USD 1 billion mark it could now punch above that?

Vinita Gupta No. So it is already above that. And the newer more complex products have enabled us to actually expand our margins. So, we would expect that to continue given the pipeline that we're bringing to market, again is limited competition products.

Shyam Shrinivasan: And my last question is just on the salesforce productivity in the India business, I think 7,700 odd medical reps. So is there any PCPM number that you can share at this point of time and where do you think this can likely reach?

Nilesh Gupta: We didn't have it off-hand, we're trying to pull it out, otherwise we'll share it with you. I think one part is we were under indexed. Therefore, we have added a substantial sales force in the last two years. Now, it's going to be programmatic. So we are going to add a few hundred representatives each year. The focus definitely has to be on productivity. We have some very nice AI measures that we're putting in place. Hopefully, those would be, interesting plays as well. We would want to focus on productivity as well, in line with maybe a little bit of increase in areas where we are lesser represented.

Shyam Shrinivasan: How many we added first half or second quarter?

Nilesh Gupta: I mean it's marginal. Not much at all.

Ramesh Swaminathan: It's been continuously increasing over the last five quarters because initially, there's a training, there's a teething period when they're not as productive. If you look at the current quarter, it's close to about INR 7.5 lakhs per month, and this has been increasing, and it still has not reached the peak, which we did about in a year and a half ago. This is because it obviously takes time to kind of train the people and so on as well.

Shyam Shrinivasan Ramesh, what was that number like? Historical?

Ramesh Swaminathan: We were closer to this market about a year and a half ago.

Shyam Shrinivasan: Okay. Like INR 9 Lakhs to INR 10 lakhs, you're saying?

Ramesh Swaminathan: INR 7.5 lakhs to INR 7.8 lakhs.

Moderator: Thank you very much, Shyam. That brings us to the end of the Q&A session. I now hand the conference over to the management for the closing comments. Over to you, ma'am.



November 8, 2024

Vinita Gupta:

Thank you. So thank you everyone for all your questions. Just wanted to respond to the Glucagon question. What we have is the kit, and we look at it as a nice size opportunity. It's roughly a USD 200 million product where we hope to be one of maybe two players in the market. So looking forward to that. And as I mentioned, we are very optimistic about our growth prospects. I mean, both this fiscal year as well as the years ahead. We know that we have still a long way to go, although we have come a long way as an organization when you look at growth trajectory as well as margin expansion. We continue to be focused on driving both, growth across our key markets not only US and India, but also the other developed markets that we can now grow with complex generic platforms or specialty, and other emerging markets based on India portfolio and in particular the GLP-1 opportunity that we see in front of us.

So looking forward to a very successful rest of the fiscal year and we look forward to connecting with you again soon. We've noted down a number of questions that you had that we had agreed to get back to you offline. So we will connect with you to respond to those. Thank you again for your time and look forward to connecting with you next quarter.

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.