August 13, 2024

BSE Limited
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051

Dear Sir/Madam,

Sub: Transcript of Q1 FY2025 Earnings Conference Call.

Pursuant to Regulation 30(2) read with Schedule III Part A Para A(15)(b)(ii) of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Q1 FY2025 Earnings Conference Call held on Wednesday, August 7, 2024.

The above is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

Rajvardhan Vishnu Satam

Digitally signed by Rajvardhan Vishnu Satam
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R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)

Encl.: - a/a

“Lupin Limited Q1 FY2025 Earnings Conference Call”

August 7, 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**

Moderator: Good evening and welcome to Lupin Limited Q1 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.

Vinita Gupta: Good afternoon, friends. I'm very pleased to welcome you to our Q1 fiscal year '25 earnings call. I have with me our MD - Nilesh and our CFO - Ramesh. We look forward to sharing with you our highlights for the quarter as well as outlook for the year ahead.

We are very pleased to start the new fiscal year on a strong note with solid double digit growth in revenues and margins both on a year-on-year and quarter-on-quarter basis. EBITDA margins at 23.3% have expanded by 290 basis points quarter-over-quarter, driven by strong commercial execution on new product launches as well as in line products, continuous attention to operational improvements as well as lower than anticipated R&D spend. In parallel, we have continued to improve our position on the quality and compliance front, having received positive FDA inspection outcomes for our Aurangabad, Somerset, Nagpur and Dabhasa facilities in the last quarter.

Our US business had a great start with strong growth sequentially and year-over-year driven by more stable in-line business, strong contribution from respiratory products both Tiotropium as well as Albuterol and new product launches like Mirabegron and Doxycycline that more than offset decline in products like Suprep® that have seen additional competition.

As we look at the quarters ahead, with continued ramp up of the new products that we have launched, additional new product launches like Pred-Forte® that we just received with CGT, Glucagon later in the fiscal year, Liposomal Doxorubicin that we're in the midst of launching at present, we expect to grow our US business at a high single-digit in fiscal year '25. Also,

our US business has returned to a strong level of margins given the shift to complex generics and strong focus on driving productivity and efficiencies in the base business.

Switching to India, we recorded 10.5% growth versus IPM growth of 8.7%, which was 21% ahead of the market. Cardiac, Respiratory, GI and Vitamins business in India grew well ahead of market. Our internal diabetes portfolio, non-licensed diabetes portfolio that is, grew at 2 times the category growth during the quarter, which was very heartening for us. We also successfully completed the carve out of our trade generics business in India to 100% own subsidiary with the objective of achieving agility, better focus and growth of this business going ahead.

From a new product launch perspective, we have been at the forefront in terms of NPLs in India and have a healthy pipeline of around 20 products which we plan to launch in the fiscal year. We are confident that our reach through our 10,000 plus reps along with our portfolio enhancements will enable us to grow around 20% to 30% higher than the market in the year ahead as we have guided in our earlier interactions.

Switching to other markets, our other developed markets grew a strong double-digit, driven by Canada due to Zaxine® - our brand business there, and new product launches like Spiriva® and Etanercept, UK due to Luforbec® and new product launches in Germany and Australia. Our other Emerging markets also grew double digits driven by Mexico, Philippines and South Africa.

On the R&D front, while Q1 has been light, we expect our spent to ramp up in Q2 and Q3 with the progress that we have in our pipeline. We expect R&D to be around INR 1,800 crores for fiscal year '25, with an increasing percentage of complex generics as we have planned over the last couple of years. We look forward to a very solid fiscal year '25 ahead with the momentum we have built in all our regions, the new product pipeline engine delivering at high gear and continued focus on the fundamentals from a efficiency and compliance standpoint. Our strategic growth drivers provide us with a clear line of sight to growth beyond the current fiscal year, both in terms of top line and EBITDA going ahead.

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

Ramesh Swaminathan: Thank you, Vinita. Friends, I welcome you all to our Q1 FY25 earnings call. The highlight of this quarter has been a strong operating performance in all our key segments, both in terms of sales and profitability which have led us to report a 23% plus EBITDA margins for the quarter.

Diving into the numbers, sales for Q1 FY25 came in at INR 5,513 crores as compared to INR 4,742 crores in Q1 last year, a growth of 16% year-on-year. However, if you exclude the USD 25 million of NCE income received last year in Q1, our sales have grown at 22% year-on-year during the quarter. We have registered robust growth across most of our key geographies. North America has grown at a strong 28% year-on-year. India business has grown at a healthy 18% year-on-year, whereas EMEA grew at 26% year-on-year. Our Growth markets grew at 27% year-on-year and API business has grown 7% year-on-year.

US business

During the quarter, the US business recorded sales of USD 227 million, a growth of 25% year-on-year and 8% quarter-on-quarter on a constant currency basis. This growth has been led by new launches offset by single-digit price erosion in base products and additional generic competition in certain products like Suprep®. Our strategy to pivot to more complex products is paying off handsomely and we have now had eight consecutive quarters of EBITDA improvement in this business. We have clear strategy to deliver consistent growth in business going ahead.

India region

Coming to India, the India business has grown by almost 18% year-on year during the quarter. The prescription business has grown 10.5% year-on-year, outperforming IPM growth by around 1.2x during the quarter. Segments like Respiratory, Cardiology, GI and the Multivitamins have outperformed IPM growth in their respective segments. The share of in-licensed products in the quarter is at 14% as compared to 15% last year, which also has a positive impact on our profitability. We have launched 28 products in FY24 and plan to launch around 20 products in FY25.

Other businesses

Revenue in our ex-India, ex-US formulations business which includes EMEA, RoW and Growth markets have increased 22% year-on-year to INR 1,185 crores and now constitutes around 21% of our sales.

EMEA

Our EMEA region which constitutes the EU region and South Africa business, registered strong growth at 26% year-on-year during the quarter. This has been driven by healthy growth in key markets like the UK and Germany from Luforbec® and NaMuscla® amongst others.

Growth markets

Our growth markets include APAC and LATAM region and they've grown at 27% year-on-year during the period. The APAC market grew by 26% year-on-year during the quarter led by strong growth in markets like Philippines and Australia. LATAM market grew 28% year-on-year in this quarter due to strong growth witnessed in Mexico.

Profit/Loss

Speaking about the P&L, other operating income is at INR 86 crores which has increased 20% year-on-year during the quarter. This increase is mainly due to higher PLI and export benefits during the quarter.

Gross margins

Coming to the profitability, Q1 FY25 gross margins were at 68.4%, up from 67.8% in Q4 and 63.8% ex-NCE income recorded in Q1 last year. This improvement is driven by multiple factors which includes better product mix, lower sales of in-licensed products, increased volumes, and also cost improvements and efficiencies, which we have undertaken over the last several quarters. Barring any unforeseen situations like geopolitical tensions in the Middle East and the like, we feel confident of maintaining gross margins around these levels going ahead.

Employee benefits

Expenses came in at INR 971 crores, increasing 15% year-on-year from INR 844 crores in Q1 FY24, translating to 17.6% of sales vis-a-vis 18.6% last year. This change is largely attributable to higher costs in terms of business growth as well as increments during this period.

Manufacturing and other expenses

Came in at INR 1,598 crores which translates to approximately 29% of business as compared to 32.5% of sales in Q1 last year, reflecting a growth of 8.6%. The expense in absolute terms is higher due to legal and professional fees and of course, higher volumes and the like. This of course has been offset by lower R&D figures.

Research & Development

R&D is at INR 350 crores, 6.3% of sales in Q1 FY25 as compared to INR 426 crores which was 8.7% of sales in Q4 last year. Our full year R&D is expected to be around INR 1,800 crores.

EBITDA

In the quarter as you see, we have made significant improvements across all lines. Our gross margins are higher. There has been increase in operating income and the higher sales ensured higher operating leverage as well. Consequently, this has resulted in driving the EBITDA margins considerably higher. Excluding forex and other income, EBITDA was INR 1,286 crores, and increased by 50% year-on-year. If we exclude the NCE income we received in Q1 last year, EBITDA is almost double on a comparable basis. Margins for the quarter were higher at 23.3% vis-a-vis 20.4% in Q4 FY'24 and 14.4% ex-NCE income which were recorded in Q1 last year.

Tax

So far as the tax is concerned, our ETR is 18.8% during the quarter. For the full year, we expect ETR to be around 20%.

Balance Sheet

On the balance sheet items, we have been focusing on operating working capital and there has been tremendous improvement there, as you can see, given the fact that the net operating working days is just about 100 days as against 105 days in the previous quarter.

ESG

On the ESG front, we have successfully committed and joined the Science-Based Target initiatives(SBTi) which drive our journey towards decarbonisation of our value chain. We have achieved a significant milestone from ISO 14001 and ISO 45001 certification across all our Indian manufacturing sites, R&D center, corporate office, etc, acknowledging our commitment to safe and sustainable operations. Our strategic interventions across water recycling, renewable energy, adoption of human rights are progressing as per plan to deliver ambitiously on the ESG goals. With this, we open the floor for discussions.

Moderator: We will now begin the Q&A session. Please raise your hands from the participants' tab on the screen to ask questions. We will wait for 30 seconds for the queue to assemble.

We will take the first question from Mr. Kunal Dhamesha.

Kunal Dhamesha: Congratulations on a great set of numbers. First one on India business, while we have grown at 18% year-on-year, you said that the Rx performance was 10.5%, right? So is there any institutional business which is built into this quarter which was not there in the last year or last year same quarter? And how should we think about the growth going forward?

Nilesh Gupta: So, you're right, it is the institution business that basically explains the difference. From our perspective, the growth in India region is 10.5%, the

India region formulation business. But when we add the other business that we sell in India or formulations, it goes to the number that you talked about. The institution business basically went from INR 15 crores to INR 121 crores. Some lumpiness in the past, I mean, INR 15 crores was not representative of the quarterly run rate last year. But I think it's going to be a good number for the GIB business. We are going to have good numbers. But I mean, for India region formulations, we'll always call out without this institutional business.

Kunal Dhamesha: Sir, last full year, what would have been this business contribution?

Nilesh Gupta: So, it's very fluid because it's exports, it's exports coming back to India. So we do report it out. Ramesh is pulling out that number. But the entire business used to be of the nature of, I believe, INR 700 something crore for the year, but that's domestic as well as export. And it's obviously on a high growth rate at this point.

Ramesh Swaminathan: So last quarter, if you're talking about it, we had about INR 63 crores of other domestic business and so on. And of course we also had diagnostics and OTC, which would add another INR 45 odd crores. So that's for last quarter. And if we talk about the previous year, it was much lower and the diagnostics, OTC, et cetera, is about 35 odd crores. And that domestic, which is essentially the GIB business would be INR 15 crores.

Kunal Dhamesha: Last year maybe was much lower than normal run rate?

Ramesh Swaminathan: Yes, that's exactly what we are saying. This is at least about 8 times higher this time around.

Kunal Dhamesha: And the second question on the US business. It seems we are seeing good performance from the new launches like Mirabegron and Doxycycline. So my question is on Mirabegron. Did we see a meaningful ramp up in the coming quarter from here on, including the launch of 50 milligram version from our side?

Vinita Gupta: We continue to increase our share on the 25 milligram and evaluate timing of launch of the 50 milligram. There is an upcoming hearing on the '780

patent, actually today. So we are monitoring that as well. But we expect to ramp up the product.

Kunal Dhamesha: And this '780 patent is for the appeal that innovator has done?

Vinita Gupta: I didn't catch the question.

Nilesh Gupta: Is it the appeal?

Vinita Gupta: Yes.

Nilesh Gupta: Yes, it is.

Kunal Dhamesha: Okay, so we are waiting for the result of that appeal and then probably will launch 50 milligrams and not launching at risk?

Vinita Gupta: We'll evaluate.

Kunal Dhamesha: And last one from my side. And I have more questions, but drop back in the queue. I think you've recently also said that Lucentis® Phase III clinical trial has been successful. And you said we will now file and it could take some time, but if you can help us with the current market structure, potential competition when you enter the market, will you be in the first wave of the launches, how should we think about it?

Vinita Gupta: So Lucentis® is a unique opportunity because it's in the ophthalmic market. And some of the ophthalmic market distributors are our current partners for the generic business. So we see a good opportunity with Lucentis® even as a late player. We believe that we should have the ability to switch share. Of course, how much, what percentage, time will tell the number of competitors. But we feel good about the Ranibizumab product for the US.

Kunal Dhamesha: Thank you and all the best.

Moderator: We'll take the next question from Neha Manpuria.

Neha Manpuria: Vinita, could you give us an update on Tolvaptan, given the litigation, what's our stance here? How should we think about this product?

Vinita Gupta: Well, it's a very certain launch at this point for us in the first quarter of next fiscal year with the win on the litigation front as well as product approval. We are gearing up to get supply together for the launch.

Neha Manpuria: And what would be your sense on post the exclusivity period, how the competition could shape up given there are other bunch of players who are also fighting the litigation on this? and I think you have a settlement too?

Vinita Gupta: We would expect additional competition, but given that this is a REMS product, a specialty distribution product, the early entrant seem to hold on to share much longer. So, we would expect it not to be a typical oral solid where you see significant erosion after additional competition. We expect to maintain a decent share even after additional competition gets in. But for us, the 180-day exclusive window itself for such a large product is a great opportunity for fiscal year '26.

Neha Manpuria: And my second question is on generic Spiriva®. If you look at IQVIA data, while not too much, we are seeing a share coming off a little bit. I know we have guided to like the 35% - 40% share is what we should be getting to this year. Could you explain the dynamics of that market? I know the innovator tried to cap pricing for the out of pocket. Is that impacting our ability to get share? How should we think about share gain from here for Spiriva®?

Vinita Gupta: So, we are seeing share at the 30% level right now based on the most recent data, which is consistent with what we have seen - some weeks it's up, some weeks it's down, but overall, roughly around that 30% level, which has been what we saw with other respiratory generics in the past, but continue to work on avenues to grow that share. I mean, what we have seen after the brand brought in the USD 35 copay is more business going towards commercial. The business is split between the Commercial and Medicare, Medicaid. And there's actually a pretty good percentage that's Medicare, Medicaid where we have a low share right now. We have a higher share of the Commercial. So that also gives us hope that we should be able to gain share given the

Commercial segment of the business, Commercial component of the product is going up.

Neha Manpuria: So, essentially the shift to the Commercial therefore helps us, right? So, the share gains should be visible in the subsequent quarters?

Vinita Gupta: We are hopeful that we should be able to grow share.

Moderator: We'll take the next question from Mr. Abdulkader.

Abdulkader: My first question is with regards to the market share in Albuterol. So, there seems to be some softening in our market share on a sequential basis as well as the share of the complex product, I think it's come down a bit. Could you help me reconcile what's the entire impact and about this market share loss? What would we have on a sequential basis?

Vinita Gupta: I mean, we're seeing market share very stable at the 20% level, so no real material loss of any customers, and it's been a pretty solid contributor to the quarter. So, no real change in market share. I mean, there was additional demand during the flu season a couple of quarters ago that would have had some impact on phasing of supply, but the market share has been fairly stable for us. There have been shifts with the other players in the market, but we've seen our customer base and shares stay pretty stable until now.

As we go forward, based on what happens with the launch of Amphastar, when Amphastar launches it, because I mean right now it looks like they are in a hold mode, and we would expect that Teva is going to file an injunction. So, we'll definitely see erosion going forward we think to some extent, but overall our share is fairly stable so far.

Abdulkader: And the second is on the Mirabegron launch. So for the base erosion and the competition in Suprep®, we are largely commenting that the launches had offset that. So, going ahead, I mean, how do we see the run rate? I know we have a limited exclusivity here, or rather co-exclusivity here, but on a quarterly basis, what's the expectation in terms of the sales run rate for this particular product?

Vinita Gupta: We don't really highlight product-wise sales, but based on what we expect from Mirabegron, given the additional competition, as well as the other products that we are launching, Pred Forte®, Glucagon, others that we have in our plan, and the Albuterol erosion, like what I mentioned, we would expect high single-digit growth over the previous year, overall.

Abdulkader: And a final one, if I may, which is a bookkeeping one. So we made a provision of close to USD 9 million. So, I mean, where exactly would that be recorded into the P&L? I'm referring to the Glumetza® provision.

Ramesh Swaminathan: It's part of other expenses line. So, that's one of those items that we flagged off even in our disclosure that we paid off about INR 75 odd crores for Glumetza.

Moderator: The next question is from Bino Pathiparampil.

Bino Pathiparampil: Vinita, just digging a little deeper in on Tolvaptan which you said you will launch next year. There are two brands of the product if I understand correctly. So, are you going to address both of them or only one?

Vinita Gupta: As far as our plans have entailed, we are looking at the whole molecule. And when we look at the molecule, the oral solid dosage form, that is the primary product for Otsuka it's USD 1.5 billion in revenues for the company. So that's the market that we're targeting.

Bino Pathiparampil: Second question on Slynd® on which I think you have a tentative approval. I think there was some hearing set for this month, August. When would that be and if it goes well, is it going to be a near term launch?

Vinita Gupta: So that's end of this month. I think it's the last week of August. And we don't know what the outcome is going to be, but we are preparing for launch in case we have a win.

Bino Pathiparampil: So if it goes well, it can be near term launch?

Vinita Gupta: Yes.

Bino Pathiparampil: And one last question. In your opening remarks, you had mentioned two - three products for the year. One, I believe, was Glucagon, another was Doxil® generic. What were the other one or two you mentioned?

Vinita Gupta: Ophthalmic, I mentioned Pred Forte®. We just got CGT approval of Pred Forte® last week, so we're gearing up to launch that product as soon as we can. We have a couple of other Ophthalmic products that we are launching in Q3. So I think Pred Forte® plus the others. But, other than injectable Doxorubicin as well as Glucagon, we should have like three or four Ophthalmic products with Pred Forte® being the largest.

Moderator: We'll take the next question from Krishnendu Saha.

Krishnendu Saha: Yes, just on the Mirabegron, how big is the 50mg? And 25mg, I suppose, last quarter we learned it was USD 700 million. How big is the 50mg?

Vinita Gupta: I think it's a little bit larger than the 25mg.

Krishnendu Saha: Any number?

Vinita Gupta: It's close to USD 1 billion.

Krishnendu Saha: And just from the annual report, when I was reading through the annual report, I saw the US revenues coming up at I think INR 67 billion. But when I do the quarter-on-quarter of disclosures, which we have for the Q4 number, it is INR 72 billion. So just trying to understand what is the difference? Could you help me out over here? So just trying to understand what was the difference?

Ramesh Swaminathan: Which region are you talking about?

Vinita Gupta: The US business.

Krishnendu Saha: So, in the US business, when you go to your annual report, you quote a number of INR 67.628 billion and over here is INR 72.462 billion on the quarterly or the Q4 number, when you look at. So there's a difference which is pretty big. So I'm just trying to understand?

Ramesh Swaminathan: That would have included Canada, North America and the like, but we could take it offline and see what are you talking about.

Moderator: We'll take the next question from Saurabh Kapadia.

Saurabh Kapadia: Firstly, on the US market, given the few launches in second half and Tolvaptan in FY26, how should we look at the US growth in FY'26?

Vinita Gupta: FY'26 should be a very strong year for us. I mean, given the current products that we have this year plus Tolvaptan for certain as well as other injectable products like Liraglutide and Risperdal Consta®, we're looking at a pretty solid year in fiscal year '26.

Saurabh Kapadia: And secondly, on the margin front, so our long term guidance or the aspiration is 20% to 23% range. So given this quarter and also next year number of products we are launching, should we expect to reach that margin level by next year?

Ramesh Swaminathan: So, from our perspective, I think three or four things to be said. Firstly, this particular quarter, there has been a lower spend on R&D. So if you go to factor that in, the overall margins could have been a little lower. And we do expect, in fact, the R&D figures to step up from next quarter onwards. There's, of course, the one-off, the Glumetza® settlement, which has come in also. So, you need to factor that in. We also have adjacencies which are not actually core to us at this stage, which also make losses. So, that has to be factored in. So, the overall guidance that we have been speaking about is essentially moving towards a core of about 23% to 24% in the medium term and we'll get there.

Saurabh Kapadia: So, how much percentage point the adjacencies are pulling down in terms of margins currently?

Ramesh Swaminathan: In OTC - we expect to break even now. We also have diagnostics and digital. We also have the API CDMO business, which is in some ways behind the curve. So, all of this put together about 1.5 to 2 percentage points.

Moderator: We'll take the next question from Bhavya Sanghvi.

Surya Patra: This is Surya here.

Surya Patra: My first question was on businesses other than the US and India, where across board, we are seeing a kind of robust growth number this quarter. Anything that is driving this and how sustainable the growth momentum there in all the regions and what is really helping it to achieve this kind of momentum?

Vinita Gupta: So, really maximizing our portfolio across different regions, the European region, for example, has the benefit of Fostair® generic that has continued to grow very nicely with limited competition. They also have one or two additional new products that are launching. So, that also will help grow the business further. Other countries - Germany, Australia have had good new product launches as well. Canada has had Spiriva® launch and Etanercept launch. So I mean, overall strong performance, commercial execution and maximizing the portfolio.

Surya Patra: So, is it that other business than India and North America is likely to gain momentum and hence increase market share going ahead? That is the kind of expectation?

Vinita Gupta: So, we expect the overall percentage of the US and India has remained kind of the same and we'll be happy if all our regions grow, to help grow the company at the double-digit level.

Surya Patra: My second point is on Mirabegron. Given the kind of litigation situation, how long this opportunity be? Whether one should think about a 180-day kind of a period for this opportunity, or it could be a relatively longer opportunity also, given - till time the outcome of the litigation is pending?

Vinita Gupta: So, it's very much dependent on the outcome of litigation as well. I mean, it could be that the exclusivity could be longer depending on what happens with the hearing on the '780 patent and it's hard to really predict, but at this point it looks like the next quarter could still continue to be a two-player market and then we could see an additional competitor. And then depending on the settlements that the other generics have with the brand, but if you assume the typical brand generic settlement, one would expect additional competition to come in during the end of the 30-month stay, typically, which is really late next year, like September next year. So again, hard to predict, but it could be extended beyond six months.

Surya Patra: Just last one point about the biosimilar, if I may. See, given the kind of situation or development that we have witnessed in the Adalimumab, are you really worried about this investment and the opportunities out of the biosimilar? I mean, what I'm trying to say is that, you'd have seen one of the players out of the 7-8 initial launches of Adalimumab have sold the product and all its rights for just USD 40 million. While the product is a USD 10 billion and minimum opportunity one would be expecting would be few hundred million dollars out of the product. And the kind of a spend in that development itself would be USD 100 million plus or near about USD 100 million. They are selling the entire opportunity rights and everything for USD 40 million. So what to understand out of this, and are you really worried about this fact?

Vinita Gupta: One, we are really glad that we didn't have Adalimumab, because the number of competitors, the competitive intensity there was really, really high. And also the brand really held onto the product for really long. So the biosimilars were competing with the brand. Having said that, Sandoz has now had some success in that marketplace. Biosimilars have really turned out to be a difficult marketplace, given the high investment, not only the development, but access to market. And then depending on what the brands end up doing, the difficulty in gaining share.

I mean, for us, Ranibizumab is more of a niche opportunity. It is a smaller product. It's not the USD 10 billion product that attracts everybody. And, yes, there are other competitors, but not in the same competitive intensity as Humira®. And like I said, that it's a more streamlined market access that we are expecting here. So, we're not expecting to make significant commercial investment to access the marketplace. We have partnerships with companies in place to really get access and gain share. So, we're not really concerned about the investment that we have made. The investment also, relatively

speaking, in Ranibizumab has been smaller than products like even Enbrel®. Etanercept for us, or what Adalimumab would have cost all the biosimilar companies.

Moderator: We have the next question from Srikanth Akolkar

Srikanth Akolkar: I have three questions. Firstly, if you can talk about the base price erosion that we have currently?

Vinita Gupta: It's a mid-single digit price erosion.

Srikanth Akolkar: And is there any change? Because even I think other companies are also talking about benign price erosion. So, has any change happened in the industry structure?

Vinita Gupta: There really has. With all of the challenges one saw with price erosions over the last couple of years, a number of companies got out of products that didn't make sense. We got out of multiple products that didn't make sense. And all of that had led to drug shortages. So, if you look at drug shortages in the US, they're at a decade high, which has been on the agenda for the policymakers, folks on the Hill. So, our customers have been very concerned as well about product exits and the economic viability of the generic business for the generic manufacturers. And as a result, we have seen more rational generic market. So, a better situation for in-line business and to really sustain the generic companies. I mean, there's been a lot of scrutiny on GPOs, there's scrutiny on PBMs, really addressing the drug shortages, which is very positive for our industry.

Srikanth Akolkar: And with the erosion quite benign right now, is it possible to call out some range of US margins now that you are talking about eight quarters of sequential improvement in the EBITDA, so is it possible to call out the margins?

Vinita Gupta: So we don't really break out region-wide margins, but it's fair to say at this point it's above the company average.

Srikanth Akolkar: Second question is on the Mexico and Philippines market. We have seen very strong growth for this quarter. So if you can call out the underlying reason and how should we see the remainder year for these businesses?

Vinita Gupta: So Mexico actually had a challenge last year with the facility being shut for a long period of time due to its GMP status. And that cleared in October last year. So after that, the business has started to ramp up. So you see the impact of the ramp up of the business back into the ophthalmic market and the private segment. So one would continue to see that growth year-over-year for Mexico for the rest of the fiscal year.

Nilesh Gupta: Philippines looks good sequentially, of course, because Q4 is light. But year-on-year again, I mean, it's a portfolio, it's new products, it's commercial excellence, we're doing well across the board in the Philippines.

Srikanth Akolkar: And that will be branded generic business in Philippines, right?

Nilesh Gupta: Yes, it is. I mean, when we report it, we report the tender part in that business as well, but this was primarily the branded generic business.

Srikanth Akolkar: And the outlook here will be continuing of the similar growth for the rest of the year?

Nilesh Gupta: Double-digit growth is the plan.

Srikanth Akolkar: And lastly on the biosimilar business, we had filed Pegfilgrastim I think a couple of years back and we also have Enbrel® biosimilar. So is it possible to update us if you are facing any challenges there? And secondly our Pune biotech park had received I think compliance issues some time back. So what is the progress on that part?

Nilesh Gupta: So, on Pegfilgrastim, yes, we had the filing, it's been processed. Moving ahead. Yes, we had the observations at the biotech facility basis which we've completed the remediation and resubmitted the application as is necessary for this. We're optimistic of clearing the facility from a compliance perspective, after which we would expect the Pegfilgrastim approval. On

Etanercept, as you know, we have commercial in a bunch of markets, Europe, Japan and the like and I think we're steadily gaining share in the product. It's still not that large.

Vinita Gupta: And the US is a little bit away. It's CY29 when the patent goes off. But as you saw we just launched in Canada. We launch hopefully soon in Australia. So we continue to expand into other markets with Etanercept.

Moderator: We'll take the next question from Tushar Manudhane.

Tushar Manudhane: Just on your guidance for the US sales growth, so let's say, for example, the litigation outcome which is expected today, so clearly that would be over and above what you're guiding for, right?

Vinita Gupta: Yes, we haven't counted that as of yet. Hopefully, we have more upside.

Tushar Manudhane: That's great. Secondly, with respect to Prednisolone, is this completely manufactured in-house or we have API outsourced?

Nilesh Gupta: The API is outsourced.

Vinita Gupta: Yes but manufactured at Pithampur.

Tushar Manudhane: So, subsequently the level of profitability would be relatively - while it is still a CGT product, how to think about profitability in this?

Vinita Gupta: It's a decent margin product. I mean, it will all depend on the number of competitors, and if anyone else gets approval before we launch. We are hoping we can get it to market before anyone else gets approved. And if we can, then it's a very nice USD 200 million brand in which we could enjoy a six-month exclusivity.

Tushar Manudhane: And apart from loss of exclusivity for say, 25mg Mirabegron, any other potential risk on the already launched product portfolio per se, which is sort of pulling your guidance at, let's say, high single digit growth for US business?

Vinita Gupta: Yes, we are assuming that we'll have some erosion in Albuterol when Amphastar launches.

Tushar Manudhane: And lastly on the API sales, this quarter-on-quarter, there has been a significant jump. So there also is there anything to call out or this is going to be a sustainable rate given that, at the industry level, the price erosion continues even over last, three to five months as well.

Nilesh Gupta: So I think there's some lumpiness which has led to the additional sales. But we are on a growth path. I think, we went in the last three - four years into a slump as far as API is concerned, COVID and after, but it's coming back. Obviously, this is not representative growth rate. We'll have lower growth rate than this, but it's definitely on the uptick as far as API is concerned.

Ramesh Swaminathan: Pen-G prices until recently were as low as 14, but it’s now coming back again. So let's see.

Tushar Manudhane: And on India business, if you could just break the Rx growth into price, volume, launches for us?

Nilesh Gupta: So the volume growth was 5%, price was 3.5% and 2.1% was new introductions.

Tushar Manudhane: So the volume growth is much higher compared to the industry growth of 0.91%. So anything you want to call out here?

Nilesh Gupta: It's been good performance. Yes, I don't think we've grown so well in the past on the volume front, you're right, but I mean, it's good performance and primarily driven by the non in-license portfolio, the in-house portfolio.

Tushar Manudhane: So, MR addition for this year on the number which is disclosed in the presentation.

Nilesh Gupta: So, I think we are at a good number on representatives now. Now I think it will be the programmatic few 100 representatives that we add each year basis new divisions and areas. I think there is a plan to add a couple of hundred this year.

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

Shyam Srinivasan: Thank you for taking my question. Just the first one on your balance sheet. We are now showing net cash, right? So you've not been in this position for some time, I believe. So just what are the thoughts in terms of deployment of capital going ahead?

Ramesh Swaminathan: We are happy about the fact that we are without debt at this stage, but it's not as though we believe that we should be a debt free company, because we obviously believe in acquisitions. We've always been acquisitive. And if the proposition really is compelling enough, we would look at that. And I also believe from a return on equity perspective, trading on equity is possible only if you have some debt. But of course, we have guardrails in terms of the total quantum of debt that we would have, which we believe that it should be about twice that of EBITDA. But that doesn't necessarily mean that I need to borrow unless there's a proposition which is compelling.

Shyam Srinivasan: So what are the areas that are priority for us in terms of either therapy or geography areas that we would be looking at?

Ramesh Swaminathan: We've always been pretty bullish about India, so if we do come across things that are compelling, we could look at that. It could be small bolt-on in terms of generics and other parts also. But we have also been very explicit about our ambitions on the specialty front.

Shyam Srinivasan: And last one, just a clarification. Ramesh, on your comments on the gross margins, right, so you said the reasons for the gross margin improvement, if you could elaborate again, and you said that this is the new sustainable 64%, is it?

Ramesh Swaminathan: No. So essentially about 68%. The reason is, of course, it's the sales mix, the kind of products that we've been bringing to the market. This time around, there is of course, being the inventory impact also. So, as you could see, there's a lowering of overall inventory in terms of consumption itself. So from that perspective, that has cost a blip of about 0.9%. So if we'd add that, the margins could have been a little higher. For sure, I think we could sustain with this given the kind of product launches that we are kind of planning for the future.

Moderator: We'll take the next question from Damayanti Kerai.

Damayanti Kerai: I have a question on your complex injectable pipeline. So, Vinita mentioned Liraglutide could be a possible launch next fiscal year. So just want to have some update on your pipeline and specifically on these peptide GLP sort of products.

Vinita Gupta: So Liraglutide, both Victoza® and Saxenda®, we have filed and based on the CRL, as I mentioned, we expect them to get launched next year. And Glucagon is the one that we would expect later this fiscal year based on where we are with the filing, with the agency. Doxil®, a smaller opportunity but launching in the next couple of weeks. So, those are the near term injectable launches. And then next fiscal year, hopefully, subject to of course FDA approval, we should have Risperdal Consta® launched as well. We just recently had an inspection for our Nanomi site and that was successful. So we hope next year we're able to launch that product as well.

Damayanti Kerai: And also if you can update on the Dulera® filing I guess that's also one of the opportunity which we were looking at.

Vinita Gupta: So Dulera®, we have a pending CRL that our team is working upon. It is taking a little bit longer to address the agency's queries but we expect in this fiscal year to be able to respond and potentially that could be a product also that is available to launch next fiscal year or fiscal year '27.

Damayanti Kerai: Coming back on this complex injectable, so you will be doing in-house manufacturing for all the product, even Liraglutide, et cetera, from your Nanomi facility or you have some partnership there?

Vinita Gupta: We have CMOs. I mean, for example, on Doxil® we have a CMO, a partner rather. And then in Risperdal Consta®, we have a CMO, where we do our manufacturing in Europe.

Nilesh Gupta: And other complex injectables would also happen from our Nagpur facility.

Vinita Gupta: Glucagon and Liraglutide would be from the Nagpur facility site.

Moderator: We'll take the next question from Amey Chalke.

Amey Chalke: Most of our questions are answered. Just one on the inhaler pipeline. Where are we in terms of filing for Ellipta®, Respimat® and also the complex injectable AmBisome®.

Vinita Gupta: So we are again pretty far along in development with Respimat® as well as Ellipta® in both platform products. The first products we plan to take exhibit batches this fiscal year. So hopefully next fiscal year, early fiscal year '26, be able to file to the FDA.

Amey Chalke: And AmBisome®?

Vinita Gupta: AmBisome®, actually we dropped it. Based on the competitive intensity there, the number of folks that got approved, we didn't think it was worth investing into the development of the product.

Moderator: So we'll take one question from Mr. Kunal Dhamesha.

Kunal Dhamesha: So one for Vinita, ma'am. Since we have seen a lot of shortages in US and there has been improvement in price erosion, but in terms of business structure, have you seen any improvement, let's say, longer term contracts, better working capital, receivable days, anything on the business front which would have structurally improved due to these shortages?

Vinita Gupta: Structurally for us there have been a lot of improvements based on what the team has been working upon from a working capital standpoint, from managing the gross to net lines, the failure to supply penalties, the back orders, the returns, all of that management has improved significantly for us over the last couple of quarters based on which one sees really limited leakage from a gross to net standpoint. So structurally, from an overall market perspective, there hasn't been a material change. There have been some new players that have entered like Mark Cuban, Amazon has got into generics in the last couple of quarters, but one hasn't seen a material shift from a channel perspective. But overall, the market dynamics have been more stable, just led by all of the pressures that led to a number of drug shortages that exists in the marketplace. So we are hopeful that this continues for the industry.

Kunal Dhamesha: And the second one. So the CGT on Pred Forte®, is it linked to the fact that anyone else shouldn't get approval before we launch the product? Is it the condition?

Vinita Gupta: So CGT products until you launch, I mean, if there are others that can get approved, they can also get a CGT. So we have our CGT status with the product. We'll have a six-month exclusivity. But we can forfeit it if we don't launch it at a certain time, 75 days after. But of course, we intend to launch as soon as we can. But if there are others that get approved before our approval, they will also enjoy a six-month exclusivity. So, then it will be shared exclusivity.

Kunal Dhamesha: But we have already got approval?

Vinita Gupta: Yes, we do.

Kunal Dhamesha: So if anyone gets approval before our launch, then they get shared exclusively. Is that correct way to understand?

Vinita Gupta: That's how we're looking at it.

Kunal Dhamesha: So then the launch should be imminent? We would be just building inventory level?

Vinita Gupta: Yes, we're building inventory right now.

Kunal Dhamesha: And one point, Nilesh, on the India business. How are we planning to offset the impact from a patent expiry next year within in-license business?

Nilesh Gupta: So, I think that's the challenge with the diabetes portfolio. So obviously we work through most of the loss of exclusivities. We have one coming up at the end of Q4. We believe that we will continue to grow diabetes through the financial year. So, right now it's some 3% odd growth. It'll actually pick up, but we will have the challenge in Q4. But once we have that in Q4, we're done. I mean, from that perspective, going forward, we should be able to continue growing the diabetes portfolio.

Kunal Dhamesha: Would we be retaining the trademarks that we have created?

Vinita Gupta: Would we be retaining the trademarks that for the brand?

Nilesh Gupta: Definitely.

Ramesh Swaminathan: We make a bid for it.

Nilesh Gupta: Yes, hopefully, we'll know soon.

Ramesh Swaminathan: But as a percentage of our sales, it's actually been steadily coming down. IL was about 16% - 17% some time ago. Last quarter it has gone up a little this time around. But in the general sense, the overall salience has been coming down over time.

Kunal Dhamesha: Because the other molecule in the same category has gone generic. Is that the correct way to understand?

Ramesh Swaminathan: It basically lasts for a particular period of time up to contracting, till they lose exclusivity. And if you do make a bid for it and we do buy it, then we continue

with it. But it's not in-licensing then. It's basically an acquisition from our perspective.

Kunal Dhamesha: And then once we do that, do we have plans to manufacture it in-house? I assume, currently we will be importing the product, right, from the innovator?

Ramesh Swaminathan: That's the intention. So, for example, we always try to do that through a B2B arrangement or in our own factories.

Kunal Dhamesha: But then the EBITDA impact would be minimal, right, even if we lose some market share.

Nilesh Gupta: Typically, market share comes down, obviously the pricing comes down, but the margin profile improves substantially. So what we see is, I mean, in the first year, you do a little lesser, but in two or three years, you get back to higher than original profitability.

Ramesh Swaminathan: The volumes surge because there's a reduction in price.

Moderator: We'll take one more question from Harith Ahamed.

Harith Ahamed: If I heard correctly, you shared a guidance of around INR 1,800 crores of R&D spends for FY25. So that's quite an increase over FY24. Just trying to understand, which are the areas that you're spending incrementally?

Vinita Gupta: So majority of the focus on R&D front is on complex generics. So the largest increase is on the respiratory products, in particular the Respimat® and the Ellipta® platforms, also Dulera® additional work that we are doing to respond to the CRL, followed by injectables. So I'd say, it's a 60% investment around complex generics in inhalation and injectables, and then some percentage in biosimilars, and the rest is oral solids.

Harith Ahamed: And the US margins, which you said is currently above company level margins, that's post R&D, is that understanding correct?

Vinita Gupta: That's right.

Harith Ahamed: And last one on the long-acting injectables front. After Risperdal Consta®, are we close to filing or are we in late stage of development on any of the other candidates there?

Vinita Gupta: I think, Risperdal Consta® was the primary one that we were interested in on - there are other long-acting injectables that we are pursuing, but more on a 505(b)(2) platform that are early stage, I would say. And we'll look forward to the Risperdal Consta® approval and launch while we progress the pipeline of the 505(b)(2)s.

Harith Ahamed: And with your permission, just a quick one on Liraglutide. You said that's one of the launches that you're expecting for FY26. So how should we think about the competitive dynamics there. Do you expect to be among the first few players to launch, or are you expecting a bunch of players to launch around market formation?

Vinita Gupta: It's hard to predict because it's a really difficult product to make and get approved for from our current experience. So we would expect that it would probably be a staggered launch with the players as opposed to everybody launching around the same time and hopefully make for a better market because of the fact that when you have a staggered launch, it's always more rational than everyone launching at the same time.

Moderator: Thanks to all the participants, I now hand the conference over to the management for closing comments.

Vinita Gupta: Thank you, everyone. Thank you for your questions. Hopefully, we've been able to respond to all the questions you had on your mind. Obviously, our team is available to address any other questions that you have. As we've shared, we are very excited about the start to this fiscal year and based on the momentum that we have across all our regions, as well as the new product pipeline, we look forward to continue to grow on a more profitable basis.

So thank you, again, and look forward to talking to you soon.

Moderator: Thanks, ma'am. And that concludes our session. On behalf of Lupin Limited, we thank you for joining us and you may now exit the webinar. Thank you.