



November 17, 2023

✓ **BSE Limited**

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**MUMBAI - 400 001.**

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
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*Dear Sir/Madam,*

**Transcript-Q2 FY2024 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, we are pleased to enclose a copy of the Transcript of the Q2 FY2024 Earnings Conference Call held on Friday, November 9, 2023.

The above is for your information and dissemination.

Thanking you,

**For LUPIN LIMITED**

**R. V. SATAM  
COMPANY SECRETARY  
(ACS - 11973)**

**Encl: a/a**



**“Lupin Limited Q2 FY2024 Earnings Conference Call”**

**November 09, 2023**

**MANAGEMENT:**

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



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**Moderator:**

Hello. Good evening, and welcome to Lupin Limited Q2 FY24 Earnings Conference Call. Please note that all participants line will be in listen-only mode. And there will be an opportunity for you to ask questions, after the opening remarks. Please note that this conference is being recorded. I now hand the conference over to the management. Thank you and over to you.

**Vinita Gupta:**

Thank you. Good afternoon, folks.

I am very pleased to welcome you to our Q2 FY24 earnings call. I have with me our MD Nilesh, our CFO Ramesh and our head of Investor Relations Ravi. We look forward to sharing our Q2 highlights and outlook for the Fiscal year.

We are very pleased to build on the momentum over the last couple of quarters and deliver significant improvement in operating margins driven by growth across majority of our regions, US launch of Tiotropium and continued focus on efficiencies.

Our US business delivered continued growth in revenues and margins for a 5th quarter in a row on the strength of a stable base business, launch of Tiotropium and overall strong performance on respiratory products. In the quarter, respiratory products contributed 45%+ of our revenues. We expect to sustain our business at \$200mn plus level now going forward with the continued ramp up of Tiotropium and other NPLs in H2 and beyond.

Our India business recorded growth inline with the market, with better than market performance in key therapeutic areas Cardiology, Respiratory, GI and Women's health that we are building. Diabetes TA which was in a de-growth mode is back to growth, and will continue to build on it in the quarters to come. As we look at the second half, we expect that the investments we made in expanding on sales force to get to a level of productivity that will help us build on our growth rate from the first half. We already started seeing gains in the start of Q3, October has been strong and we expect to continue that in the rest of Q3 and Q4 for our India business.

Apart from US and India, other regions performed well too. In particular Europe recorded strong growth due to ramp up of generic gFostair in our direct markets like UK and Germany as well as through partners in other parts of EU.



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On the R&D and pipeline front we have continued to build on the momentum with both material FTF and complex generics. We were very pleased to get key product approvals like generic gTolvaptan and generic gXywav in October that will drive big part of growth in next couple of years, in particular gTolvaptan. Our pipeline is now positioned well to evolve our business into complex generics with Inhalation, Injectables and complex Ophthalmic products given the Pithampur Unit 2 clearance.

On the compliance front we have continued to make progress and are committed to ensure that we get all our sites to a consistent and sustainable level of compliance. With the strong focus on delivering the pipeline coupled with compliance gains, we can now see a clear path to sustainable growth over the next few years for our business.

We are delighted to deliver strong performance in the first half of this fiscal year and look forward to executing on our New Product Launches, continued momentum in India & other markets with a strong focus on sustaining and improving our operating margins in the second half.

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

**Ramesh Swaminathan:** Thank you, Vinita. Good evening Friends, Seasons Greetings to you and your families. I welcome you all to our Q2 FY24 earnings call. On the last occasion that we met, we mentioned that we would strive to achieve around 18% EBITDA margin by Q4 of the current year. I am happy that we have delivered on our promise, in this quarter itself.

Now, diving deeper into the numbers. Sales for Q2 FY24 came in at INR 4,939 crores as compared to INR 4,091 crores in Q2 last year, a growth of 20.7% YoY. On a QoQ basis, the company reported growth of 4.2% and 8.9% after excluding NCE income, over Q1 FY24.

We have registered robust growth across most of our key geographies. North America has grown at a strong 40% YoY and 17.4% QoQ. India business has grown at 6.8% YoY whilst EMEA grew at 24% YoY. Our API business registered growth of 7% YOY.



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Moving on to US Business - During the quarter, the US business recorded a sales of \$213 mn registering a growth of 34% YoY and 18% on QoQ basis. Just to indicate the size of the ramp up, this number was \$159 mn in Q2 FY'23. This growth has been led by New Products and by also our legacy products maintaining their market share. I am happy to share that our strategy to build complex portfolio is bearing shape and today, inhalation products are more than 40% of our US sales.

Coming to India, the India Region Formulations business (IRF) has grown by 6.9% YoY. Our growth excluding NLEM is 8.9% YoY. As per IQVIA, all our key segments except for anti-diabetes, have grown faster than the market in the quarter including cardiovascular space, respiratory, gastrointestinal (GI) and gynaecology. Even in the anti-diabetes space, our non inlicensed portfolio has grown at 10% vs IPM category growth of 4.9%. Currently the inlicensed portfolio constitutes around 13% of our IRF business vs 15.5% in FY23.

Speaking about EMEA region, which constitutes our EU region business and South Africa business, has performed exceptionally well during the quarter with a strong growth of 24% YoY. Growth in EU has been driven by our inhalation business going strong with products like Luforbec and Beclu gaining additional share and entering newer markets. EU also saw increased tender sales. I am delighted to share that we recorded our highest ever sales in Germany during the quarter.

Moving to the margins front. Coming to the profitability, Q2 FY24 gross margins are at 65.5% which has increased 170 bps from 63.8% ex NCE income in Q1 FY24 and materially from 58.1 % in Q2 last year. This improvement was driven by multiple factors which include better product mix, lower share of inlicense products, commodity deflation, increased volumes and realization of savings from few of the cost improvement initiatives like freight and other things we took on.

Employee Benefits expense -Employee benefits expense at INR 861 crores, has increased 11.5% YoY in Q2 FY24 which translates to approximately 17.4% of sales as compared to 18.6% of adjusted sales (excluding NCE) in Q1. and 18.9% in Q2 last year. While there has been a reduction in percentage to sales due to our cost optimization initiatives, I would like to mention that there is an



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offsetting impact due to the field force expansion which we undertook last year and other new initiatives.

Manufacturing & Other Expenses - Q2FY24 manufacturing and other expenses came in at INR 1,552 crores which translates to approximately 31.4% of sales as compared to 32.5% of adjusted sales (excluding NCE) in Q1 and 30% in Q2 last year. The YoY increase is on account of higher volumes, higher spends in R&D, increased consultancy charges for nitrosamine impurities, increase in selling, promotion and travelling expense in India due to field force expansion and the like.

R&D is at INR 376 crores (7.6 % of sales) in Q2 FY24 as compared to INR 338 crores at 8.0% of sales in Q2FY23.

The increase in R&D YoY is on account of investment in newer platforms of biosimilars, injectables and the like. For the full year, we expect R&D to be around INR 1,500 to INR 1,600 crs.

EBITDA: This has resulted in driving the EBITDA margins higher. Excluding Forex and other income, EBITDA was at INR 923 crores, up by 113% YoY. Margins for the quarter were significantly higher at 18.7% vs 14.4% in Q1FY24 (ex NCE income) and 10.6% in Q2 last year.

Moving on to ETR front, ETR was 22.9% in Q2 against Q1 FY24 of 18.9%. The ETR for the full year is expected to remain between 21%-22%.

PAT - Profit after tax for the quarter is at INR 490 crores demonstrating a stellar growth of 278% YoY. Diluted EPS is at INR 10.72 per share (face value of INR 2 per share).

Going on to Balance sheet - Operating working capital was at INR 5,676 crore as on Sept 30, 2023 which translates into 103 operating days. This has reduced from 119 days at end of the previous fiscal.

Net Debt at the end of the quarter stands at INR 1,806 crores which reduced from INR 2,527 crores at the end of March 2023. Gross debt has reduced by INR 720 crores during this period.



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Friends, I would also like to report on initiatives on the ESG front. I would like to mention an important update on the ESG front. We have accelerated our ESG efforts at a significant pace over the last 2 years. We have now also received the external validation of our efforts in the form of latest assessment by the S&P Global Corporate Sustainability Assessment, and it is with great pride that I announce our ESG score of 68, as of Oct 27, 2023. Our journey on S&P Global CSA (erstwhile DJSI) began with a score 17 in 2021, and last year, we marked a step forward with a score of 46. Today, we stand is 68 which places us at 95 percentile of the Global Pharma Industry. We will continue our efforts and gain ground in the years to come.

With this I would like to open the floor for discussions.

**Moderator:** Thank you very 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. Thank you.

So, the first question is from Banssi Desai. Please go ahead, ma'am.

**Banssi Desai:** Thank you for taking my questions. So, my first question is on the U.S. business, so while Spiriva looks like has contributed meaningfully in Q2 and so has Darunavir, if one were to exclude these two products, have you seen sequential growth in the U.S. base?

**Vinita D. Gupta:** Yes, actually we have seen our inline products pretty stable, growing a bit and the new product launches contributing as well. I'd say Darunavir was launched in Q1, so there was pipeline build in Q1, so the Darunavir level in Q2 is obviously lower than Q1.

**Banssi Desai:** Okay, that helps. And what is your sense on the price erosion levels in the market, any different from what we saw in Q1?

**Vinita D. Gupta:** Yes, we've seen a level of stabilization at that mid-single-digit level on our baseline products, in line products. So hopefully that continues.

**Banssi Desai:** Got it. And secondly, on Spiriva itself, our initial expectation was that this product probably will see ramp-up similar to what we saw in Albuterol, but



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clearly it looks like, it has done better than that. So, how should we look at market share ramp-up here and any visibility on the AG launch?

**Vinita D. Gupta:**

Yes, so the ramp-up has been pretty much along the lines that we anticipated. We expected that it would start at 20%-25% level, and then as we looked at other analogs, Advair and other inhalation products, over a year or so, build up to 35%-40% level, and we're seeing that right now. Our substitution rate is 25%. So, it's hard to predict when AG would launch and if AG would launch, but at this point we are just working hard to keep up with the demand as well as make sure that we scale up the business effectively for the product.

**Bansi Desai:**

Got it. I have more questions, I'll join back in the queue.

**Moderator:**

Thank you very much, Bansi, for the question. We'll take the next question from Neha Manpuria.

**Neha Manpuria:**

Thanks for taking my question. Vinita, if we do think Spiriva ramps-up to 35%-40% market share in the next year. A, would this require, in your view, more pricing action from us, to go after this market share? And second, if that is the case, should we then expect the current base that we've reported to see a step-up over the next few quarters? Because in your opening comments, I think you mentioned that we'll keep the base at 200 plus, but shouldn't we see a step-up from the current base if we get to the 35%-40%?

**Vinita D. Gupta:**

Yes. So, Neha we would expect pricing to be stable as we ramp-up the product. We don't see any additional entrants in the near-term. So, we don't see a reason for price not to be stable unless we see, a challenge in substitution. But like I said, substitution is along the lines of what we had anticipated. So, it's been a very effective launch from our team.

I'd say that, in Q2, we have some effect of the pipeline fill on Spiriva that we're continuing to see in Q3, but we think it might level off a little bit as, other inventory with our customers, gets into sync with the product substitution. And, therefore, we think that, certainly Tiotropium will continue to ramp-up, especially into the next year. But when we look quarter-after-quarter, we might see some impact of inventory correction over the next couple of quarters. And, as we also lose exclusivity on a couple of other products where we have exclusivity, we might see some downside. Of course, we have





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products that help us grow the business, which gives us confidence that both in fiscal year '25 and in particular in fiscal year '26, given the Tiotropium ramp-up plus injectables plus ophthalmic products that we have on the new product launch calendar, we should grow the business pretty well.

**Neha Manpuria:** Got it. And, I remember you once mentioning that, you think you have enough capacity to get to your fair share. Should I assume the 35% to 40% is the fair share that you were talking about and, capacity is not an issue, therefore you've given that number?

**Vinita D. Gupta:** Yes, we have built capacity not only for the U.S., but also for our other markets. So, in the next 6 to 12-months, we expect to launch in Australia, Canada, Europe, multiple regions that we built capacity for. So we are well-positioned.

**Neha Manpuria:** Got it. Ramesh, on the, cost side, I understand that the employee cost obviously has gone up this year with the MR addition that we've seen. But the other expenses also seem to be, inching up. It went up last quarter on a quarter-on-quarter basis. It's gone up again this quarter, on a sequential basis. Other than the SG&A spend associated with the India business, is there anything else that we are investing in outside of R&D which is leading to this quarter-on-quarter increase?

**Ramesh Swaminathan:** Firstly, I would like to stress that you should see this, vis-a-vis the previous quarter where there's, of course, been an increase of, operating leverage of just about 1.2%. But going on to on a year-on-year, yes, there has been, an increase which is close to 26%, but I would also rush to add that you should look at the level of activity, in terms of, the volumes of API and formulations that have grown significantly. That's actually kind of reflected in the inventory build-up, and that actually translates to in slightly increased, gross margins, which in turn kind of, reverts back to a higher increase from our expense base itself.

But I would also again add that, there is, of course, an element of one-time expenditure, which is also contained in here. So, our focus on driving down costs is still very much there, and we expect to kind of keep it on a leash around the levels that we just spoke about for in the quarters to come.

**Neha Manpuria:** Sorry, what was this one-time expenditure that you're alluding to?



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**Ramesh Swaminathan:** The one-time expenditure is, is captured because of essentially the expenses that we incurred on the CDMO spin-off, essentially the stamp duties and other costs we incurred on that. And we also took some provisions, relating to some issues that we had out here.

**Neha Manpuria:** So what is the base, cost, excluding all of these one-offs, just to get a sense of what the fair number should be going forward?

**Ramesh Swaminathan:** I would say that it should be closer to the 30% mark.

**Neha Manpuria:** Including all of it?

**Ramesh Swaminathan:** Yes, around that, so give or take based again on the level of activity and the like.

**Neha Manpuria:** Got it. Thank you so much.

**Moderator:** Thank you so much, ma'am. The next question is from Damayanti Kerai. Go ahead, ma'am.

**Damayanti Kerai:** Yes. Thank you for the opportunity. After a remarkable improvement in first half in terms of operating performance, how should we look at margin trends ahead? So, as you said earlier expected 18% margin by end of this fiscal but it came a bit earlier and now things seems to be on improving path. So how should we see margin trajectory from here on?

**Ramesh Swaminathan:** So, we think, in so far as America is concerned, the overall, the sales there should hover around, the \$200 million mark and they would of course be ramp-up in other parts including India. So I would actually expect, the growth trajectory to kind of continue and the second half would also be around the 18% mark, in the third and fourth quarters.

**Damayanti Kerai:** So, second half broadly around 18% margin.

**Ramesh Swaminathan:** Yes.

**Damayanti Kerai:** So maybe for the full year we could be in higher teens.



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- Ramesh Swaminathan:** It's obviously because the first three quarters are in the 18% and 14.5% in the first quarter, you can average it out.
- Damayanti Kerai:** Okay, and just want to understand, ma'am mentioned in her opening comment that now \$200 million plus level is sustainable for the U.S. business and that includes Spiriva and all other new launches, right? Or how should we look at that?
- Vinita D. Gupta:** That's right.
- Damayanti Kerai:** Okay, and just another question on U.S. side, how much is branded portfolio contribution right now of the total U.S. sales?
- Vinita D. Gupta:** It is small, it's under \$5 million for the quarter.
- Damayanti Kerai:** Under \$500 million, okay.
- Vinita D. Gupta:** \$5 million.
- Damayanti Kerai:** \$5 million, okay. Yes, sure. And my last question is your presentation mentioned you are building up quite well on the complex project side, 40 plus injectables and then 20 plus inhalers et cetera. In next say two to three years, how many filings we can see on the complex opportunity side? Inhalers, injectables et cetera, and if you can also call out some near-term key filings which you are expecting.
- Vinita D. Gupta:** Sure, so majority of our R&D focus has been on the complex generics, in particular inhalation and injectables, ophthalmics as well as first to files, exclusive first-to-files in particular. And we have got a good pipeline in place right now to drive the business growth towards complex generics. Already a good part of it in the U.S. is now respiratory. But as I look at the next two years with the pipeline that we have in place, on the ophthalmic front, given the Pithampur Unit 2 clearance, multiple ophthalmics, five or six products that we expect to bring to market in the second half of this fiscal year as well as into the next fiscal year. We have products like Bromday, Bromsite, Loteprednol, Prolensa, all that we're expecting approval for and then launch over the next couple of years.



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On the injectable front, we have a good pipeline now in place, multiple products in development, a few products that we expect to launch in the current fiscal year. We think Ganirelix, Famotidine will launch this fiscal year and then next fiscal year we hope to launch Glucagon. That would be a material one for us and then depending on litigation outcome also, Liraglutide in fiscal year '26. And then lastly, I would say on the injectable front, Risperdal Consta, a long-acting Risperidone out of Nanomi should come to market by fiscal year '26. So, both ophthalmics and injectables ramp-up in the second half of this year, but more so in fiscal year '25.

And then, also the first-to-file oral solids like Tolvaptan in fiscal year '26. We're very pleased to get that approval in October, our goal date, As well as, products like Mirabegron and Oracea and Doxycycline. we expect both approvals as well as litigation outcome over the next couple of months that will enable us to confirm launch dates, but we expect to launch in the next, two years.

**Damayanti Kerai:**

Okay, that's helpful. Thank you very much.

**Moderator:**

Thank you so much, ma'am. The next question is from Karan Vora. Karan, you can go ahead.

**Karan Vora:**

Yes, thank you for taking my question. So my first question is on the India business. So, going forward, assuming the IPM grows at, say, high-single-digits, do you think even on a base which has the in-licensed diabetic product which went off patent, we can still outperform the IPM over the medium-term, or it will be slightly tall?

**Nilesh Gupta:**

Yes, Karan, that's clearly the plan. The plan is to continue growing it better than the market. Diabetes is the one category that has been a challenge for us, but that also has come around to growth now for us. So, certainly we would expect growth to continue better than the market for the mid to long-term.

**Karan Vora:**

Okay. And how do you how do you split this or say if you grow at 10% how do we split that out into price and volume?

**Nilesh Gupta:**

So usually, it's I think for the industry it is more or less similar. I think you usually see 2% to 3% volume increase. You see another couple of percentage points from new introductions and the balance comes from price increase.



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- Karan Vora:** Okay, thank you. Second question on Spiriva. So just needed some clarity. So, basically is this understanding correct that because this was the first quarter of launch there would be some amount of channel filling and so Q3 and Q4 the amount of Spiriva which you book would be lower than Q2. So that could impact your U.S. Q-o-Q growth or is that understanding, correct?
- Vinita D. Gupta:** Yes, there may be some phasing. We're still tracking it very closely. So, we'll find out over the next couple of months. But we would expect that there will be some levelling off in the next month or so.
- Karan Vora:** Okay. And just two quick ones on U.S. business. So, any update on Revlimid launch?
- Vinita D. Gupta:** That is out a couple of years for us. So, it's, I think, fiscal year '26, if I'm not mistaken.
- Karan Vora:** Okay, and lastly, at the current run rate, is the U.S. business EBITDA and PAT breakeven or not, if you could give some qualitative sense? Thank you.
- Vinita D. Gupta:** It is EBITDA accretive to the company average margins. And, we hope that we'll continue at this pace and improve further as we, ramp up the business.
- Karan Vora:** Yes.
- Moderator:** Thanks, Karan. The next question is from Kunal Dhamesha.
- Kunal Dhamesha:** Thank you for the opportunity. First one on the biosimilar, is there any update on the Pune facility and Pegfilgrastim filing for us?
- Nilesh Gupta:** Yes, I can take that. So we had the EIR, which was issued by the FDA. We identified areas of improvement in the EIR, which were actually underway. And we hope to send an update to the agency by March, post which we would follow up for an approval.
- Kunal Dhamesha:** Sure. And what would be our strategy here for commercializing? Let's say if we get approval in FY25, will there be any field force required, front-end commercial infrastructure.



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**Vinita D. Gupta:** Yes, so we're tracking the market very closely right now, and of course, waiting for the site and product approval before making concrete plans. But, as the market evolves, the access model gets a little bit simpler as we see it, with established channels in the marketplace.

So, we are constantly tracking, and plan even with a direct-to-market salesforce effort to really have a very targeted niche salesforce that can double-up with our injectable business, so we can have some operating leverage as opposed to having a single product investment. So, watching that carefully, and we also have, apart from our own plans and potential to launch, we also have interest from partners. And we're going to closely track our OBI product development to determine what is the best route for us to go.

**Kunal Dhamesha:** So, and any update on the Ranibizumab and that is also something that we are developing, right?

**Nilesh Gupta:** So, on Ranibizumab, we are well on our way on our clinical trial. We've got the last patient in; it's still going to be about a year to do the filing itself. But this is the clear filing for the next fiscal.

**Kunal Dhamesha:** Sure, and the second question is on the seasonal product uptake in the U.S. Typically during this time around there is flu season and we have Cephalosporins as well as Tamiflu. So have we seen any uptick, in this quarter or probably we could see it in next quarter.

**Vinita D. Gupta:** We've seen some uptake in this quarter in anticipation of a flu season and the season has just started, so we just started the last couple of weeks tracking. So it has ramped up but we'll have to really get into the next month or two to see how strong the flu season is going to be and it certainly has ramped up but it's at a level below last year right now.

**Kunal Dhamesha:** So, like-to-like, it's level below at least from October and November is the way to look at it.

**Vinita D. Gupta:** That's right.

**Kunal Dhamesha:** Okay. Thank you. All the best and happy Diwali.



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- Vinita D. Gupta:** Thank you. Happy Diwali to you as well.
- Moderator:** Thank you Kunal. The next question is from Nitin Agarwal.
- Nitin Agarwal:** Hi. Thanks for taking my question. See Vinita when we talk about 25% market share on Spiriva, we take into account the entire portfolio of Spiriva, Respimat inhaler and HandiHaler both are we just talking in terms of the single strength?
- Vinita D. Gupta:** I'm talking about the HandiHaler.
- Nitin Agarwal:** As a percentage of that market. But how do you see the substitution happening from Respimat inhaler? I mean, how do you see that playing out?
- Vinita D. Gupta:** Actually, the encouraging sign for us was, in the last couple of years, we have seen the HandiHaler decline versus Respimat, that the brand has been working hard to convert. They had also moved their couponing strategy to the Respimat to drive hard conversion. We actually saw in the last couple of months a flattening of, so no decline in the HandiHaler, which is a promising sign. And we hope that as we continue to ramp-up the product as it gets utilized, that it will definitely flatten the decline or, hopefully take some share from the overall molecule.
- Nitin Agarwal:** And secondly, you talked about, U.S. stabilizing around \$200 million now. When you take a two year view from here on, I mean, where do you see the next milestones, something like \$250 million thereabouts, when you start to hit that at a consistent level?
- Vinita D. Gupta:** I'd say that, next year is going to be a ramp-up year for us, both with Tiotropium as well as the other product launches. And certainly, fiscal year '26 is one where we see with, on the strength of the new product launches. Tolvaptan is going to be a material one for us. Potentially Liraglutide depending on of course approval as well as litigation and the ophthalmic injectible ramp-up. We expect to be at that closer to the \$250 million a quarter.
- Nitin Agarwal:** So, when is the Tolvaptan launch? What timelines are you looking for that, potentially?
- Vinita D. Gupta:** It's fiscal year '26.



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**Nitin Agarwal:** Okay. And last one, we've seen a reasonable ramp-up in our non-U.S. export geographies, across a bunch of these geographies. Any color on, the kind of scale up which has come through and where, where are these from profitability perspective and contribution to our overall profitability as we go forward?

**Vinita D. Gupta:** Certainly. I mean, apart from the U.S., when we think about, apart from U.S. and India, Europe has been a very strong contributor this fiscal year so far, and we expect that to continue over the next couple of years. Likewise, Australia, Canada, all of them had a pretty strong run rate over, over the last couple of quarters driven by complex generics. I mean, if you look at Europe, Fostair generic has become our largest product there, and we're continuing to ramp it up. So, respiratory has become a big part of the focus in Europe.

In Canada as well, we're looking forward to launching Tiotropium soon. Australia as well, we expect to launch Tiotropium soon. I believe, we are under-indexed right now in the ex-U.S. developed markets. Our complex generic portfolio inhalation, also biosimilars and injectables really will enable us to grow these markets as well. So, they become a larger part of the company over the next two to five years.

**Nitin Agarwal:** So, this group as a whole, can it sort of compound in mid-teens over a period of time?

**Vinita D. Gupta:** For sure. Already, Europe has ramped up. Canada and Australia are already at a good level. So, we would expect them to be in the mid-teens.

**Nitin Agarwal:** Last one. In fact, on the Consta product, where are we on the filing and approval process? You talked about '26 launch on that.

**Vinita D. Gupta:** We are filing it this month. It's in the final stages of the filing. And we would hope by fiscal year '26, as that gives us a couple of cycles to get approval.

**Nitin Agarwal:** Thank you so much, and best of luck. Happy Diwali to you.

**Vinita D. Gupta:** Thank you.





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- Moderator:** Thank you so much, Nitin. We'll take the next question from Bino Pathiparampil.
- Bino Pathiparampil:** Good morning and good evening. Hi, Vinita just a follow-up on Spiriva, you had mentioned earlier that you're seeing a substitution rate of 25%. How is this defined? What does that mean?
- Vinita D. Gupta:** That's a prescription ramp-up rate that we are seeing of the generic versus the brand HandiHaler.
- Bino Pathiparampil:** Okay. And how, one bottle or one canister, however you call it, how long does it typically last for a patient? One month, two months?
- Vinita D. Gupta:** I think it's a 60-day supply if I'm not mistaken.
- Nilesh Gupta:** It's a 30 day.
- Vinita D. Gupta:** 30 days.
- Bino Pathiparampil:** 30 days. Okay. So if substitution rate is 25%, then 30 days we should be hitting 25% market share, right? I mean, am I, is there something wrong in that assumption?
- Vinita D. Gupta:** I think so, that's just right.
- Bino Pathiparampil:** Okay. And second?
- Vinita D. Gupta:** That's the kind of unit share, we are seeing the unit and prescription share, coming close together at this point.
- Bino Pathiparampil:** Okay. Are you talking this about only new prescription? I mean, people going for refills are still, the substitution rate is not that high. Is that the case?
- Vinita D. Gupta:** No. We are seeing overall substitution, not just NRX.
- Bino Pathiparampil:** Yes, Okay. Understood. Second, a follow-up on Mirabegron, you mentioned that in a couple of months you are expecting some litigation outcome, which will decide the launch date. So, could you let me know, in case the litigation



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outcome is favourable then what could be the launch date and if it is unfavourable then what could be the launch date?

**Vinita D. Gupta:** So, we have prevailed on one major patent in litigation in the district court that's on appeal right now. We have settled on another and the brand has continued to file patents that we have been battling. We are actively working on our litigation strategy to determine how soon we can launch.

**Bino Pathiparampil:** Okay, so what is the earliest possible or the latest possible? Is there a range that you can give?

**Vinita D. Gupta:** I wouldn't be able to share an actual launch date. It's fair to say that we are actively working on this one and the fact that we won on the major patent was very heartening for us, gives us confidence of our ability to launch.

**Bino Pathiparampil:** Understood. Just last one on Nascobal and Diastat. Are these now already kind of part of the base? Is it currently in Q3, or we are yet to ramp up?

**Vinita D. Gupta:** No, so we are yet to ramp up. Actually, Diastat we launched last week. It was a fairly challenging product, but the team has launched it effectively. And Nascobal we expect to launch in the next week. So, both of those will contribute to the growth in Q3 and Q4.

**Bino Pathiparampil:** Thank you. I'll join back in queue.

**Vinita D. Gupta:** Thank you.

**Moderator:** The next question is from Sanjay Khullar. Sanjay, you can go ahead.

**Sanjay Khullar:** Okay. First of all, I would like to compliment Vinita for delivering excellent results. I have a couple of questions. Madam, where do you see our company in over next two, three years, as you mentioned that we are on a steady growth plan. So next target is \$5 billion, maybe three to five years down the line.

Second question is, when do we surpass the record profits achieved during Shri DBG's times, we achieved record profits. So when do you see we achieve this in next two, three years?



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**Vinita D. Gupta:** Very good questions. Both the long-term prospects on the revenue front and profitability, and our goal is really to get our company back to consistent growth on revenues as well as improve our profitability, so profitable growth more than just growth. So, on the revenue front, we see, I mean, fiscal year '26 is going to be a material year for us, as I mentioned in the last couple of minutes, given the material launches, as well as ramp up of current products, continuing to solidify the gains that we have made. And then I'd say in a five-year time frame, we expect the overall company business to grow substantially.

**Sanjay Khullar:** Yes, fantastic.

**Vinita D. Gupta:** And both across the U.S., as well as India, and as well as, other parts of the developed markets that we are currently under-indexed on, they should be a larger part of our business in five years. I'd say on the developed market side, U.S. as well as Europe, Canada, Australia We would see majority of our portfolio, two-thirds of it switching to complex generics based on the investment that we've made and the execution so far, inhalation, injectables, really contributing a material part of our growth over the next five years.

On the profitability front, we have come a long way over the last year and a half, still a long way to go. Our highs of 20 margins certainly are aspirational for us. Right now, we can see a path over the next few years to get to a good 20% plus. Mid 20s is our goal, to really close the gap with our peers. There's no reason why we should be below that. But as we continue to look at the company prospects beyond five years and look at investment plans in particular in areas like specialty, which long-term are our aspiration for our organization. We'll have to determine what kind of investments we make. So, we'd hope to get to 20% plus, then the mid-20s and then we'll determine what's the best way to grow our organization for the long-term.

**Sanjay Khullar:** Okay, and one last thing, madam. I used to meet DBG when I used to be a friend with him. He used to say Lupin will be number one pharma company from India. So, I'm sure your dream will also be that. So, do you see happening in next five years, seven years down the line, madam?

**Vinita D. Gupta:** What we are, given the complexity of our business across globe, India being a big part of it, U.S. being a big part of it, and our chosen strategy of going into



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complex generics as opposed to a broad-spectrum generic company, I would say that, at this point our focus is to be the best in what we do. We want to be a leader in the areas that we have chosen, so like respiratory is one that is turning out to be one of our biggest growth drivers for the organization globally. We're already a big player in India, and we want to be, a material player ex-India as well. It's a big part of our business in the U.S., as well as a growing part in other parts of the world. So, I'd say, the areas that we choose to be in, we'll target to be the best.

- Sanjay Khullar:** Okay, madam. Thank you very much and wish you a Happy Diwali.
- Vinita D. Gupta:** Thank you. Happy Diwali to you as well.
- Sanjay Khullar:** Thank you.
- Moderator:** Thanks, Sanjay. Before, we proceed, just a reminder to all the participants to raise your hands for further questions. We'll take the next question from Ankush Mahajan.
- Ankush Mahajan:** Thanks for the opportunity. Ma'am, we have U.S. revenue in the range of \$211 million now. So, this run rate, could you give me some sense of what kind of a run rate that we can expect in upcoming quarters? Because you already have inched to \$211 million from \$181 million.
- Vinita D. Gupta:** Yes, I mentioned \$200 plus million is what you should expect.
- Ankush Mahajan:** For the upcoming quarters.
- Vinita D. Gupta:** That's right.
- Ankush Mahajan:** Thank you, ma'am. Thanks.
- Vinita D. Gupta:** You're welcome.
- Moderator:** Thank you. So, I think that pretty much ends, brings us to the end of the Q&A session. I now hand the conference over to the management for closing comments. Thank you.



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**Vinita D. Gupta:**

Thank you, friends. Thank you for all your questions. And as we mentioned, we are very excited about the progress we have made so far. We look forward to a very successful second half of the year and building from there into the next two fiscal years. So, look forward to strong quarters ahead and reporting the same back to you, all of you.

Given the holiday season, wishing all of you a very Happy Diwali and a prosperous new year. Have a wonderful holiday weekend and look forward to speaking with you again next quarter. Thank you.

**Moderator:**

Thank you so much, ma'am. So, on behalf of Lupin Limited, that concludes this conference. Thank you for joining us. And before we sign off, here's wishing all of you all a very Happy Diwali. And now you may exit the webinar. Thank you very much.