“Lupin Limited Q1 FY2024 Earnings Conference Call”

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MANAGEMENT:

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Moderator: Hello. Good evening, and welcome to Lupin Limited Q1FY24 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 Q1 FY24 earnings call. I have with me our MD Nilesh as well as our CFO Ramesh. We look forward to sharing our Q1 highlights and outlook for the fiscal year.

We are very pleased to start the new fiscal year strong with continued momentum across our major regions, improving compliance position, multiple new product approvals and improvement in operating margins. Our India business is firmly back to double digit growth and the US business margin has continued to improve. We expect to see material improvement in the rest of this fiscal year as we launch Tiotropium and other new products in the US as well as our sales force expansion in India starts yielding expected productivity from Q2 onwards.

Our India business recorded an 11.5% growth QoQ and 10.2% growth YOY and this is after the NLEM impact as well as CIDMUS brand that we had in the base last year. Cardiology and Respiratory TA's grew better than market growth, our Diabetes TA that has been a challenge for the last many quarters due to loss of exclusivity of key in-licensed brands is now back to growth as planned by our team.

As we look at Q2 and beyond, based on the momentum we have and the enhanced productivity from the sales force expansion, we now feel confident of consistent above market growth.

Switching to the US, our margins continued to improve for the fourth quarter in a row on the strength of a stable base business, continued performance of key products like Albuterol, Lisinopril and Suprep, launch of Darunavir where we had exclusivity on the 800 mg strength. In addition to revenue growth and better product mix and therefore better gross margins, we also continued to deliver on reducing SG&A as well as distribution cost. With the approvals of products like Tiotropium, Cyanocobalamin, Diazepam gel and other approvals now likely due to Pithampur Unit 2 Warning Letter clearance, we have a rich

pipeline of products to drive revenue and margin growth in the US for the rest of this fiscal year and beyond.

Apart from India and the US, all other regions performed well too in particular our Institutional TB and API business did extremely well during the quarter.

On the R&D front, our spend increased QoQ, driven by patent litigation on key products, Ranibizumab clinical trial and long-acting Risperidone completion. On the NCE front, we were very pleased to receive the milestone from Abbvie for our program advancing into the clinic. Our pipeline is now positioned well to evolve our business into complex generics with inhalation MDI and DPI, injectables from Nagpur and partnered products, as well as complex ophthalmic products from Pithampur Unit-2.

On the compliance front we have made progress with positive outcomes with Pithampur Unit-2 warning letter clearance that will enable us to launch Ophthalmic products filed from the site in particular products like Prolensa where we were first to file as well as other ophthalmic products next year. that will enable us to launch important products like PROLENSA, where we are first to file, as well as other ophthalmic products next year.

Out of the five sites we had under warning letter, we have now cleared three and continue to make progress on our remediation efforts in Tarapur and Mandideep. We are committed to ensure that we will get all our sites to a consistent and sustainable level of compliance.

We are excited to start fiscal year '24 on a strong note and look forward to executing on our new product launches, continued momentum in India, and operating margin improvement as we grow our business in the year. We expect fiscal year '24 to be strong with quarter-after-quarter improvement in revenues and profitability.

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

Ramesh Swaminathan: Thank you, Vinita. Friends, welcome to a refreshing set of numbers. On the last occasion that we met, we did promise you that our results and margins would get to be better in successive quarters. We have endeavoured to live up to that guidance.

Sales for Q1 FY24 came in at INR 4,742 crores as compared to INR 4,330 crores in Q4 FY23, a growth of 9.5% QoQ. On a YoY basis, the company registered a growth of 31.6% over Q1 FY23 sales of INR 3,604 crores. The sales of Q1 FY24 included $25 mn income from Abbvie for key milestone of initiation of Phase 1 clinical trials. Excluding the same our sales were 4,537 crores which represented a growth of 4.8% QOQ and 25.9% YOY. Our sales growth this quarter has been robust across all our key geographies. The US market registered a growth of 3.6% QOQ and 49% YOY (in local currency terms) whilst the India branded business registered a growth of 11.5% QOQ and 10.2% YOY. The API business registered growth of 4.5% YOY and 32.1% QOQ.

During the quarter, the US business registered a growth of 3.6% (in USD terms) on QoQ basis as sales went up to $ 180.7mn from $ 174.5mn in the previous quarter. In Q1 FY'23 the sales were only $ 121.3mn. Products like Darunavir, Suprep contributed to this robust performance. We are continuing to maximizing the high value products resulting in a sustainable and profitable US business.

India Branded Formulations business sales improved by 11.5% QOQ and against previous year the sales improved by 10.2%. Our growth excluding Cidmus and NLEM is a robust 13.60%.

API business sales grew by 4.5% on QoQ basis due to higher 7ACCA sales as core cephalosporin API sales recovered handsomely. Similarly, on YoY basis sales growth was at 32.1% led by higher sales thanks to good demand pick up in the cephalosporin API.

Q1 FY24 gross margin is at 65.4% and at 63.8% ex NCE income, as compared to Q4 FY23 gross margins of 59.6.% (a Variance of about 6.8%). The improvement in margins quarter on quarter is driven by US as well as India. In the US, we had NPL launches, better mix, higher price realization in few products and reduction in freight expenses. The margins also expanded due to higher better mix both in IRF and API apart from other reasons. We do expect this margin to sustain

We have improved significantly from last year Q1, when our gross margin was 55.3% to the current levels of 63.8%. The improvement, again, was driven in US margin as Q1 margin last year in US was at all-time low. Improvement in India and API margins are also the other major contributors to the overall margin improvement year on year

Q1FY24 is at INR 853 crores which translates to approximately 18.5% of adjusted sales vs INR 773 crores in Q4FY23 which translates to approximately 18% of sales. The same was INR 779 crores or 24% of sales in Q1FY23.

The QoQ increase is mainly due to annual increments which were to the tune of 7.5% across the globe.

Q1FY24 manufacturing and other expenses came in at INR 1,472 crores vs INR 1,303 crores in Q4FY23. These expenses were reported at INR 1,192 crores in Q1FY23.

The QoQ Increase is on account of higher spends in R&D, increased consultancy charges for nitrosamine related impurities, increase in selling and promotion expenses in India due to field force expansion. Same reasons were also responsible for the year on year increase.

R&D is at INR 368 crores (7.8 % of sales) in Q1 FY24 as compared to 1,280 crores in full year FY23 which was 7.9% of sales. The increase in R&D QOQ is on account of investment in newer platforms of biosimilars and injectables.

Our EBITDA came in at INR 879 crores in absolute terms, representing an 18.5% margin. Excluding one-time NCE income, Forex and other income, our EBITDA margin was at 14.4% or 651 crores, reflecting an improvement of 50 bps in comparison to the previous quarter. The improvement in EBIDTA is primarily driven by higher gross margin, partially offset by higher expenditure in R&D, higher employee cost due to salary hikes and higher PLI income in base quarter.

The Effective Tax Rate was 18.9% in Q1 against FY'23 ETR FY'23 of 36.9%. The lower ETR is primarily on account of US subsidiary which has seen a turnaround, offsetting the NOLs of prior year, and the ETR was also lower on part of Sikkim tax benefits.

The ETR for the full year is expected to remain between 21%-22%.

Operating working capital was at INR 5,195 crore as on June 30, 2023 which translates into 103 operating days. This has reduced from 119 days at March 31, 2023.

Net Debt as on June 30, 2023 stands at INR 1,310 crores which has come down from 2,500 crores at the end of Q4FY23. We have done repayment of packing

credit loans in India and also retired some debt in Australia. With this, we could 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. So, bear with us, please.

So, the first question is from Damayanti Kerai. Please go ahead, ma'am.

Damayanti Kerai: Yes. Hi, good afternoon. My first question is, can you update us on your launch plan for Spiriva in the U.S. in terms of preparation, and when you are going to launch it, and also your view on the market, specifically market shift which could possibly happen from Respimat to Handihaler. So that's my first question.

Vinita Gupta: Yes, so we are actively working towards a launch this quarter. We expect to launch it later this quarter. And well time will tell if we can really switch share back from Respimat to Spiriva. I mean, at this point we believe that we will be the only generic in the marketplace. We haven't heard of an authorized generic launching, so we will look to really find a way to substitute as much as possible to our generic.

Damayanti Kerai: Okay. So second quarter launch towards the end. That's your target for this product.

Vinita Gupta: That's right.

Damayanti Kerai: Okay. And ma'am, earlier, I think you mentioned the addressable market size for you is around $1 billion? Or like what is the addressable market you'll be working for this launch?

Vinita Gupta: Yes, around that $1 billion size.

Damayanti Kerai: But that includes both HandiHaler and Respimat, right? It's a total market, not only the HandiHaler part.

Vinita Gupta: No, the Respimat was on top of that

Damayanti Kerai: It's on top of that $1 billion market, which we're looking at.

Vinita Gupta: That's right.

Damayanti Kerai: Okay. My second question is your other expense trend. So, Ramesh, obviously mentioned what has led to quarter-on-quarter increase, as well as year-on-year increase. But should we take the current quarter number as the base going ahead? Or we expect further increase in this number? And I'm asking specifically because you have been talking about cost saving goals, et cetera. So where we can see benefit of cost saving on say other operating expense or some other line item.

Ramesh Swaminathan: Yes, so let me explain. We do expect, in fact, the gross margins to kind of sustain at the current level. So it is certainly going to be elevated, but you would also appreciate we've been talking about, in fact, a higher quantum of investments on the sales and promotion front, especially in India, and we've added about 1,300 people in Q3, Q4 of last year. So obviously, this will also be reflected in higher expenditure, on account of that, it will then commensurate increase in terms of the sales itself.

This particular quarter there has been increase in nitrosamine expense on account of nitrosamine quality assurance and the like, on account of compliance, and of course, there is an R&D spend, which is on the higher side. We expect the R&D to kind of sustain at these levels. Of course, there has been a provisioning for non-product-related litigation. That's kind of one time.

So, the parts of this, which will certainly continue into the future. But what we actually had guided for is successive increase on the EBITDA front. And that's what we would be concerned about. And you will certainly see this in quarter two, three, and four.

Damayanti Kerai: Okay. And my last question, since now you are more positive on growth outlook ahead, and then profitability also. So, do you inch up your margin guidance for FY'24? Earlier, you mentioned you'll be somewhere like mid-teen margins for FY'24 with exit rate of high teens.

Ramesh Swaminathan: Yeah, so what we had said was perhaps in the fourth quarter, you could see an exit rate of over 18%. We're sticking to that, and we are confident of actually exceeding that.

Damayanti Kerai: So you can exceed 18% plus or say high teen margins towards the end of this fiscal.

Ramesh Swaminathan: 18% in the fourth quarter, and above the 15% mark, we guided for in the past, for the full year.

Damayanti Kerai: Okay. Thanks. Thanks for your response. I'll get back.

Moderator: Thank you so much, ma'am. So, the next question is from Neha Manpuria. Please go ahead, ma'am.

Neha Manpuria: Yeah, thanks for taking my question. My first question is just a follow-up on the R&D that we mentioned. So Ramesh, when you say, we would likely to sustain it at this level, does it mean as a percentage of sales, this is what we should be factoring in. On an absolute level, this is what we would continue to spend.

And a follow-up on that is on the biosimilar pipeline. I think, Vinita, you called out that we are trying to build out a biosimilar and an injectable pipeline. So, if you could give us some update on when we can see monetization from this, both on the biosimilar and in the injectable front, when can this be a meaningful contributor?

Ramesh Swaminathan: On the first part of the question, let me clarify that what we expect to kind of sustain is an absolute amount. As a percentage of sales, that potential could come down, because we expect the sales to certainly go up. Second part, Vinita, could answer.

Vinita Gupta: Yes, on the biosimilar pipeline, as you know, so far, we have commercialized Etanercept, and we continue to work on launching Etanercept in new markets. That's on the plan, on the cards for the next couple of quarters with partnership through Viatris, now Biocon.

And we continue to work with the FDA, to try to get clarity on our inspection outcome at our Pune site for pegfilgrastim. So, we hope to be able to get clarity on that soon.

The R&D, that I had spoken about was the clinical trials spend on ranibizumab that we had incremental spend this quarter versus the previous. And we continue to pursue ranibizumab in particular for the U.S. as well as through partners into other markets as well. So that's on, as far as the biosimilars go.

On the injectables front, we are actively adding to our pipeline right now with both 505 (j) as well as 505 (b) (2) opportunities. With the Nagpur approval -- FDA inspection and approval, we now expect to get multiple product approvals out of the site for the U.S.

Certainly later in this fiscal year, we hope to be able to get products like Glucagon onto the market. In this last quarter, we launched Thiamine, which was out of our partnership with Caplin Point.

And so we have a combination of both internal products as well as partner products that we expect to help build the injectables business, starting this year, but more so also into the next fiscal year and beyond. We have within our pipeline a large percentage of the products that we are pursuing now are injectables.

Neha Manpuria: Yes, that's helpful. And just on Spiriva, what sort of ramp up should we expect for Spiriva? Would it be, given that we are the sole generic, you talked about there not being an AG, so would this be a much, sharper uptake versus what we saw in albuterol or should we assume a much more gradual uptake, in the generic?

Vinita Gupta: So when we looked at the analogs, when we look at the other DPI, in particular Advair, the substitution that we saw was a ramp up over time, starting at 25%, 30%, and then building up to the 40% plus level. So what we are planning for right now is a similar kind of substitution rate, hopefully, enhanced with some of our efforts.

We have active marketing efforts in terms of HCP awareness, pharmacy awareness on the generic. But, still potentially going to be looking at a ramp up over the next couple of quarters, and certainly over the next two years.

Neha Manpuria: And you think we get to a fair share, by middle of next year, the 40% substitution that you're talking about?

Vinita Gupta: We hope so.

Neha Manpuria: Okay. Thank you so much.

Moderator: Thank you so much, ma'am. So before we move on, this is just a reminder to everyone to please raise their hands on the participant tab.

Yes. So the next question is from Surya Patra.

Surya Patra: Yes, thanks for this opportunity. And congrats for the good set of numbers, ma'am. My first question is on the authorized generic possibility in Spiriva. And I think in the previous quarter you have been anticipating that but so far there

is no development on that side. So is it fair to believe that there is no authorized generic even next year kind of timeline?

Vinita Gupta: It's hard to predict that. We would hope, but we can't really predict what the brand is going to do. I mean, at this point, it looks like, they're not planning to launch authorized generic imminently. And based on the substitution rate, maybe they will wait to see next year where we get from a substitution standpoint to determine whether they launch or not.

But the positive for us is, we had expected an authorized generic and we don't expect it anymore. So our launch quantities, our supply chain planning has been geared towards a higher volume, obviously.

Surya Patra: Okay. So, do you find any rationale or why there is not an authorized generic, because -- so basically, a kind of sizable opportunity. So is it that there are no -- since we have not seen any filer for this, so hence the scope of authorized generic is not coming that way, that is a way to think or how is it that?

Vinita Gupta: I think it's just given that we are a sole generic on this, and substitution is going to be over time. Perhaps the brand is thinking that they can maximize the brand value, while we ramp up our share. That's the way I think about it. Yes. I mean, additional authorized generic will be additional competition from a pricing perspective.

Surya Patra: Sure. Yes, yes, of course. My second thing is that on the (Inaudible) side, whether you have already seen the kind of meaningful or large portion of the anticipated benefit in the quarter or that is to be seen in the subsequent period?

Vinita Gupta: No, we've seen a good amount of benefit in the quarter, in particular for the 800-milligram strength where we were exclusive. We had a load-in into the quarter, but we'll continue to see it in the next quarter as well.

Surya Patra: Sure. And just for Ramesh, sir, if you can just clarify what are the tax benefits from the Sikkim side that you are getting? And so, whatever the tax rate guidance that you have given, that is only for the current financial year, because of this Sikkim benefit and may not be there next year?

Ramesh Swaminathan: It will be sustained. Essentially, what we were saying is there's a higher quantum of sales coming from Sikkim, and there's, of course, the benefit of a tax-free regime out there. Second benefit is essentially because we're now

generating profits in America, and previously that was not indeed the case. To that extent, we still have NOLs of a large quantum. And the quantum of tax that you actually pay on the profits would be to that extent, about 80% is still exempt because the NOLs carry forward, and you pay only on the balance. And of course, there is state taxes as well. The total absolute quantum of taxes paid across entire Lupin would potentially be lower because of all of that resulting in a lower ETR.

Surya Patra: Okay. So, when you're saying the profitability of U.S. has gone up, so that is excluding of this milestone payment --

Ramesh Swaminathan: Yes. Absolutely, excluding. I'm talking about operating -- based again on the portfolio that we have out there.

Surya Patra: Okay. Just last one question, ma'am. See, in fact, sometime back in a media communication, I think you indicated about even entering into the basic research kind of activity. So, discovery research and potential spending that side. So can you update on that? See, initially there was a kind of thought process that we will be hiving of our discovery research. Then in the interim, there was a kind of say about potentially looking into that again. And so hence, at this juncture, what is the kind of final thought process there? And what is the kind of investment likely beyond the R&D spend what we are talking about?

Vinita Gupta: Actually, we have curtailed our spend significantly on the NCE front. As I think we shared even last quarter, we had a discovery effort that we pretty much closed down, which was the bulk of the investment.

And we decided to pursue the three pipeline programs to see if we can really get any signal in terms of efficacy on the programs. So, in trials that we're doing in India, at a fraction of what it will cost us in the U.S. So right now the effort is pretty low-single digit in terms of millions of dollars. And, one program in the clinic in phase one.

And, if we see positive results, really it will lead to licensing effort or an effort to finance it through external funding. We don't have plans to commercialize these -- the NCEs ourselves or take on major risk on the NCE front ourselves.

Surya Patra: Okay. Sure. Just last one bookkeeping number question. See, sir, can you just clarify what are the consultant spend that you have indicated. Means quantum-wise for the quarter?

Ramesh Swaminathan: We don't want to actually talk about quantum. Essentially this is -- essentially relating to QA testing for nitrosamines and the like. There's a step-up on, in fact, of what we spent in Q4, and that's what is recorded out here. I'm only saying that this is not going to sustain into the long-term, it will perhaps peter off over time.

Vinita Gupta: Well, we are working towards remediation on the nitrosamine front. And the industry has a goal of trying to get October this year, end of this year, as much as possible, the FDA and the other regulatory authorities have set guidelines on the nitrosamine front that we are trying to meet. Therefore, the spend is ramped up right now, but it should come down in the second half of the year.

Surya Patra: Thank you, ma'am. Thanks a lot. Wish you all the best.

Moderator: Thank you Mr. Patra. We'll take the next question from Mr. Krishnendu Saha.

Krishnendu Saha: Thanks. We are already six months into the year practically and we guided for 18% exit. So, what is the view on -- how do you see that 18% being sustainable over FY '25? That's question number one.

And Vinita, we're supposed to launch Spiriva at the end of the quarter? So, it's already August. Have you started shipping some quantities out there?

Vinita Gupta: Yes, we have. So we already have production well underway and shipments as well underway. But to your first question on what gives us the confidence of 18% exit? I mean, just based on where we are right now and the products that we plan to bring to market, Spiriva in particular will be a material one. Apart from that, we have cyanocobalamin, we have diazepam and other smaller products.

But then later in the year, we also have products like PROLENSA, where again, we have exclusivity. And at the end of this fiscal year, we expect products like Mirabegron, where based on the litigation outcome, we think that there's an upside opportunity. So, all of this put together in the current year, plus then leading into the next fiscal year, gives us the confidence that we should be able to sustain the momentum on the margin.

Krishnendu Saha: I see. So, we could sustain the FY '24 exit margins into 2025.

Ramesh Swaminathan: And perhaps exceed that also going forward.

Krishnendu Saha: Yes. I'm just trying to understand the launches, we are preparing for a normal or soft launch or we're going full force?

Vinita Gupta: No, we're going full force on -- are you talking about Tiotropium, in particular?

Krishnendu Saha: Yes, yes.

Vinita Gupta: Yes, yes. We're going full force, but we expect the generic substitution rate to ramp up over time.

Krishnendu Saha: Yes. I'll come back in queue.

Vinita Gupta: Yes.

Moderator: Thank you very much. The next question is from Saion Mukherjee.

Saion Mukherjee: So, on Indore, now the site getting cleared, how should we think about launches, anything which is, seen meaningful still there that can come out of Indore. If you can give some colour on that. And also would like to hear on complex assets where are we in terms of development, if you can give us an update and when you expect some of the key filings to happen.

Vinita Gupta: Yes. So out of Indore, in particular, the ophthalmic products, we see a nice opportunity around in five or six products that we have filed from the site. Some of them were just pending because of facility, which now should happen. Like PROLENSA is the first of the pipeline opportunities that really is an upside for us this fiscal year.

The other, we have products like Brimonidine, products like Prednisone, like five or six products that are meaningful out of the ophthalmic facility, and in particular now with the shortages in the marketplace on the ophthalmic front, we see a nice opportunity for these products. We should have PROLENSA this year. And we think that three or four products are going to be next year, next fiscal year.

To your second question on the evolution of a pipeline into complex generics, on the inhalation front, of course, MDIs and now with Spiriva, DPI, nicely expanding our portfolio franchise. And we are actively working on other DPI platforms, Ellipta in particular, we have made significant progress. We hope to report at the end of this fiscal year, a material milestone on that front, on one of our products. On Respimat also, we have made significant progress, and we'll make more so in the next fiscal year. But Ellipta, we have made significant

progress so far. On the MDI front, there are a couple of products that we are pursuing.

And then we are actively also taking a look at the whole move towards Green Propellants in the U.S. and Europe, and working on both the current product of 505 (j) to the current product, as well as the novel propellant versions of the MDIs, that can enable us to potentially have some differentiation and exclusivity in the marketplace.

So, I'd say that strong progress on the DPI front and Respimat, and some progress on the MDI front, especially given the Green Propellant move, we are watching that carefully, so that we don't have to - we make an investment and have to redo a product completely. So, that's on the inhalation front.

On the injectables front, as I mentioned earlier, we are adding to our pipeline very actively right now. We have multiple 505 (j) products and 505 (b) (2) products that we have added to our pipeline already. Nine products in active pipeline this year have been added to the injectable pipeline. And apart from that, I'd say, I think back on the respiratory front, we also have nasal sprays that we are actively working upon.

And lastly, I'd say, on the implants and devices, we have made good progress on products like Nexplanon and Mirena, where we have developed equivalent versions of the products and are actively working on the clinic right now.

Saion Mukherjee: Okay. Thanks for that explanation. When I look at the R&D spend today, let's say, you'd be doing, say, INR1,400 crores annually. Is it possible to sort of split up like how much approximately you're spending on all these inhalation assets and biosimilars. If you can take us through some split on the R&D front?

Ramesh Swaminathan: More than 50% would potentially be for the complex ones.

Vinita Gupta: Yes, I think it's like 20% on inhalation, 20% on injectables, roughly, and 10% on biosimilars.

Ramesh Swaminathan: Yeah.

Vinita Gupta: The like.

Saion Mukherjee: Okay. And just one last question, if I can. So, you've got 25 million from AbbVie. I think couple of years back, we had like two large deals signed. So, are there any milestone payments that we can have some visibility this year, next year?

I mean, is there any visibility on the licensing income that you can get on these out-licensing deals that you had?

Nilesh Gupta: I think it's going to be a couple of years out to the next milestone. I think what's happened is the risk profile of the product has improved significantly. So, potentially the probability of a future milestone goes up, but it's going to be a couple of years out for the next milestone now.

Saion Mukherjee: Understood. Okay. Thank you. Thank you very much.

Moderator: Thanks, Saion. The next question is from Kunal Dhamesha.

Kunal Dhamesha: Hey, hi. Thank you for the opportunity, and congratulations on a good set of numbers. First on the product, this Myrbetriq. On the litigation front, is this a new patent that the innovator has kind of sued the generic filers over or this is our old patent litigation?

Nilesh Gupta: So there is a new patent that the innovator is suing everybody on, but we feel confident about the outcome of that.

Kunal Dhamesha: Okay, perfect. And would you kind of give some market sizing for that product?

Vinita Gupta: It's like a sizeable $2 plus billion product. So significant.

Kunal Dhamesha Okay. And do we have an exclusivity here or it's going to be a multiplayer launch at day one?

Vinita Gupta: We believe there's going to be limited number of players, day one.

Kunal Dhamesha: Perfect. And since we have talked a lot about the injectable business or injectable pipeline, so do we have some form of aspiration as to where we see this injectable business probably two-year, three year down the line for the U.S. market?

Vinita Gupta: We do. We do have a sizeable build in for building it to a multi-100 million dollar business, but there's still work to be done, to get there. Our current pipeline gets us to $100 million dollars, but we'd like to be well above that in the next 5 years.

Kunal Dhamesha: And this 100, so the pipeline you're talking about is a filed pipeline and not the pipeline under development. That'd be the correct assumption?

Vinita Gupta: We will reach near to $100 million, from products that we expect to launch within the next five years. Already that gets us to 100 plus million. But like I said, we'd like it to grow it to a different level.

Kunal Dhamesha: And from the plant perspective, which are the important plan for this 100 plus million opportunity. One, I think is

Vinita Gupta: It's just Nagpur.

Kunal Dhamesha: Nagpur. Okay

Nilesh Gupta: Injectables are over here in Nagpur.

Vinita Gupta: Yes.

Kunal Dhamesha: Perfect. And did I hear correctly that we have completed our trials for the Risperdal Consta?

Vinita Gupta: Yes, we have successfully.

Kunal Dhamesha: Okay. So, when are we planning to file that?

Vinita Gupta: Next quarter.

Kunal Dhamesha: And any probable timeline in terms of approval for these kind of long-acting injectables?

Vinita Gupta: Well, we hope that the agency will, just given that there is no approval, hopefully, the agency will engage with us on trying to get the product approved sooner than later. But we're expecting, after we file, two-plus years or so to launch.

Kunal Dhamesha: Perfect. And last, if I may, on the future inhalation pipeline where we have talked about the Ellipta product, right, I believe the Ellipta product segment is more like DPI, and they are also like more than one API, right. That is where last time we hit a roadblock in terms of generic Advair, which was a mix of two APIs. So, what gives us confidence there? What has changed? What have we learned from the generic Advair, which would help us crack these products?

Vinita Gupta: Yes, generic Advair certainly was a big challenge for us, partly due to the fact that it was not under our roof. We were doing the development in a

partnership with Ceylon and Poland, which made it a challenge for us. But this is being developed in Coral Springs.

Our team is excited about the development. They've made progress already on the dual formulation, the two-drug combination, and are working on the three-drug combination right now. So, the learnings that they had from Advair, they certainly have applied here.

And, we feel good about the fact that we have a good prototype in place to scale up.

Kunal Dhamesha: Sure. Thank you and all the best.

Vinita Gupta: Thank you.

Moderator: Thanks Kunal. So next question is from Mr. Shyam Srinivasan.

Shyam Srinivasan: Good evening, and thank you for taking my question. Just the first one on the U.S. generic pricing environment. We've had multiple companies during this quarter talk about an improvement / stabilization. The only challenge that I have is many of them have one-off opportunities in terms of special products that are there as well. So, you don't have that at least currently.

So, I just want to understand what are kind of the trends you're seeing on the base business and maybe you could elaborate around shortages, inventory changes that are happening, or any new business opportunities. So, just the entire piece, and how Lupin is probably seeing things at this point of time.

Vinita Gupta: Yes, certainly has changed a bit, compared to the last few years. And we see price erosion really at a low-single digit percentage at this point on inline products, on our base portfolio. And that's as a result of the fact that over the last couple of years, there's been so much pricing pressure, it pushed a number of companies out of markets. We got out of a number of products that we had announced last year, that didn't make sense. They were not economically viable anymore. Likewise, a number of our peers got out of products.

And I think that has led to drug shortages. Right now, drug shortages is a huge concern that we've heard from folks on the hill, in the U.S., as well as from the FDA, as well as other stakeholders. So, I think the fact that it had become such a tough environment for the generic industry finally has struck home and has led to this price stabilization, which we hope will continue going forward.

Shyam Srinivasan: So, Vinita, the low-single digit, this is on the base of say last year, which is making it, right? do you think like the next nine months of the fiscal, we'll see similar, or you think this is transient and will go back to given how the whole GPO structure is that we will go back to higher price erosion, or you think this is sustainable? So just repeating the question again.

Vinita Gupta: Yes, we hope it's sustainable. It's hard to predict.

Nilesh Gupta: The in-line portfolio right. So for example, today we have exclusivity on darunavir (Inaudible), as more competition comes into that you can see erosion there. But you're saying for the in-line products.

Vinita Gupta: For the in-line products, we think that it should be low to mid-single digit.

Shyam Srinivasan: Got it. Very helpful. The second question is on the India domestic piece, right? I think earlier guidance was for growth to come back Q2. So, we've seen it one quarter earlier, perhaps. And I think if you exclude Cidmus, if I remember the opening, we had 13%, right? So, what's happening? Yes, what is happening right here? I know we have added quite a few MRs over the period. So just want to understand what are the checkboxes that are happening right in the India piece and what's the outlook for the remainder of the year?

Nilesh Gupta: Yes, I think it is more what was going wrong. Just to clarify, it was 13.6% if you adjust, but 10.2% unadjusted. You know, I think it's just a focus, right. So, like we said, the real pain point was the in-license portfolio, which was facing exclusivity challenges, certain products like Cidmus that went out of the portfolio as well. The core business was growing at a very healthy rate. And we always guided towards that.

And you just see that reflection coming out now. I think we still have to see productivity gains from the representatives that we've added. Some of those divisions, most of those divisions have already started performing, but you'll see even better results from that Q2 onwards.

But I think this is just the core business kicking in. So respiratory, we're growing pretty much at double the market rate. Cardiology, we're growing ahead of the market.

Diabetes, we're growing, which we were actually de-growing before. So I think it's the three core therapies which are focused on chronic, which is coming through.

We're doubling down on India. So, from our perspective, the representatives have resulted in six new divisions. There's a new extra urban division that we've launched as well. So, I think there's a lot of really good energy in India and we would certainly expect this growth rate to continue.

Shyam Srinivasan: Yes, Nilesh, just last follow up and I'll stop after that. Any other products that are going off patent in the innovative portfolio that we may need to be aware of in the next three, six months?

Nilesh Gupta: Yes, so I think we have one Ondero which will go off patent this August? So the Ondero is going to go, I think, a lot of that is already reflected in the reduced pricing that we have, maybe a little bit more. And I believe that in 2025 we have one other product as well.

But this was kind of the mainstay, the big products which are going at this point of time. I don't think we'll get into a position where we see, very tepid growth in India again, but there is going to be lumpiness in some of the quarters, as some of these exclusivities go.

Shyam Srinivasan: But we stick to the kind of double digit, at least it was from quarter to last time you spent, but full year now you can do double digit in India, looks like.

Nilesh Gupta: Yes, absolutely.

Shyam Srinivasan: Great. Thank you, and all the best.

Moderator: Thank you so much. The next question is from Harsh Bhatia.

Harsh Bhatia: Yes. Thank you. Just one quick clarification in terms of the injectable portfolio that we have been talking about for, let's say the expected filings and the expected launches, without getting into particular products. Would it be fair to assume that most of these, or a large part of these have been filed through the Nagpur unit 2, because that's the injectable, the main injectable facility, right?

Vinita Gupta: Yes.

Harsh Bhatia: Okay, so over the next one or two years, whatever is there in terms of the launches and expected filings would be through Nagpur Unit 2.

Vinita Gupta: Well, also some partnered products.

Harsh Bhatia: Okay. All right. Thank you.

Moderator: So, since we have addressed most of the questions, we'll just wait for 10 seconds for any further questions to be taken because we can't see any raised hands currently.

Krishnendu you can come-in

Krishnendu Saha: Sir, on some of the Indian piece, your strategy, we have 9,100 MRs right now. So, how do we see going ahead. Do we see like -- I'm just looking at Mankind, I'm seeing they're high inroads in tier II and beyond. So -- and what kind of, do we look into any space like consumer health or something like that? Is there any other differential strategy which would be something different from what we're doing right now?

Nilesh Gupta: So, right now, I think most of the representatives that we've added have resulted into new divisions. And the focus has been on decluttering and focusing on key brands. Like I said, there is an extra urban pilot that we've started as well. That is something that I would hope that we would scale up, but we'll have to go through that and see how it does before.

The primary focus at this point of time has been decluttering, and focusing on building bigger brands. So we're not -- it's not that much of regional expansion at this point of time, but we certainly would hope for more going forward.

We don't see a big expansion this fiscal anymore. Obviously, we want these to stabilize. There's possibly one more division that we're going to launch in this financial year. But then after that, we would programmatically expect to add 500 odd representatives each year.

Krishnendu Saha: Any missing therapy areas, which we'd like to acquire or something. We are heavily into chronic?

Nilesh Gupta: Amongst our peers, we're obviously, heaviest on the chronic side, but we're not number one in any. So, I think there's significant headroom to grow in Respiratory, in Cardiac, in Diabetes. But I think Women's Health is shaping up very nicely. GI is shaping up very nicely. Even in like ophthalmic picking up, we're severely underrepresented in Oncology, in the CNS space. So, lot of headroom from my perspective, and that's what we're going after.

Krishnendu Saha: Right, so Respiratory is at 1,000 crores for us right now, and we should cross the Diabetes and the CVS space by say another year or two?

Nilesh Gupta: Yes, I think we were already at the 1,000 crores mark on both of those. Respiratory was the last to get to that number, but certainly there's a lot more room to grow. We're still number three only in both of those therapy areas in Cardiac and in Diabetes.

Krishnendu Saha: Thank you. This is a good direction. Thank you.

Moderator: Thanks, Mr. Saha. Next question is from Alok Dalal.

Alok Dalal: Hi. Sir, you incorporated a subsidiary Lupin Manufacturing Solutions for undertaking contract development and manufacturing activities. So, what is the plan here? What kind of investments will it require? And let's say isn't there a case for conflict of interest here with the generics model that you have?

Nilesh Gupta: Yes, I think we've just incorporated it at this point of time. I think it's a thought that we have, but I think to enable anything in life, we needed to first incorporate a subsidiary to really consider any next steps at all. There is an opportunity on API, which I think large generic companies are not doing well with.

Several of our peers have shown good progress in this front. There's a whole bunch of new players who are in the API and intermediate space, which are not large generic companies. So I think the intent is that there is an opportunity to be chased here, but I think we're talking a little prematurely. We still need to finalize our internal plans before we have anything more here. And we will come back to you guys once we finalize our plans.

Alok Dalal: Nilesh, just one question on capital allocation with diagnostics and then with CDMO. Wouldn't it be a better off opportunity if you invest in the core business itself?

Nilesh Gupta: Yes, so I think lion's share of our incremental capital allocation is going towards the India region, and into other geographies where we expect high growth. And that will be continuous as far as the parent company is concerned. As far as, just this kind of subsidy was concerned, eventually you would obviously go for external capital on something like this as well. So, it's not your own capital alone that would get allocated there.

Alok Dalal: Okay, okay. Thank you for taking my questions.

Moderator: Thanks, Alok. The next question is from Gagan Thareja.

Gagan Thareja: Yes, so the first question is on the gross margins. While you pointed out to an improvement in mix there. Would softer API and solvent prices also have benefited and could you enumerate what?

Ramesh Swaminathan: Yeah, in a general sense, yes. You know, there has been, in fact, softening of prices across except for excipients, others have actually been coming down API, KSM and chemicals and solvents for sure. So, but there's of course a bit of a lag effect, because it's been coming down and there is of course some of it, which would be captured the cost of production, but not necessarily sold during the course of the quarter itself. But will certainly, give us a benefit in the quarters to come.

Gagan Thareja: And do you also avail of any PLI benefits. And if so, can you enumerate the number?

Ramesh Swaminathan: It's there in the other operating income. So that's a component that is there.

Gagan Thareja: And this quarter the emerging markets piece has been slightly weakened probably not just for loop in, for some of the other companies as well.

Ramesh Swaminathan: There are two or three parts there essentially the first was, South Africa has had a bumper Q4 in anticipation of a price hike in Q1. And that obviously, it in fact subdues the results, the outcomes for Q1 itself. Likewise in Philippines, in Mexico we have in fact an issue in terms of the plant which will get sorted out. So, all of these actually brought down the overall result in the first quarter.

Gagan Thareja: But how should we think of this space for the year?

Ramesh Swaminathan: I think it will pick up, actually this resonates in fact with past patterns, Philippines and South Africa and we have seen this trend kind of persist over years. And of course, Mexico, the plant issues that get sorted out. So, it's just a question of time.

Gagan Thareja: Last one on Suprep, do you see yourself maintaining your current run rates going ahead or generic competition will materially impact Suprep?

Vinita Gupta: Yes. So far, we have sustained the levels over the last couple of quarters, and haven't really seen any imminent additional competition coming in.

Gagan Thareja: Do you see this for certain happening in the second half, for your generic?

Vinita Gupta: No. It's hard to predict. We just don't see anyone coming in the next couple of weeks or months.

Gagan Thareja: Thanks. I'll get back in the queue. Thanks.

Moderator: Yes, sir. Thank you so much, Gagan. Vibha, you can go next.

Vibha R: Okay. Just a question regarding the expansion into adjacencies, regarding digital therapeutics or even diagnostics, or as you just spoke about CDMO. But are these opportunities that are really far off that you're looking at, just as a de-risking or is it like you have serious plans for these new segments?

Nilesh Gupta: So I think the core India prescription business is going to be the main focus area. As far as diagnosis is concerned, we're already starting to see some synergies with the core prescription business. Digital, again, feeds into our expertise in the Cardiac space, and it is an extended offering from that front.

If you want to do a meaningful play into CDMO, then yes, that would be a different play compared to the other stuff that we would do, but we obviously have capabilities for doing that.

No, I think as far as the core business model is concerned, we are extremely upbeat on India. We're extremely upbeat on the complex generic story in the U.S. At some point of time, we want to build out the innovation piece all over again. The emerging markets have always been double digit growth markets for us, with pretty much better than company average EBITDA. So, I think the core focus remains on the business as is, we've got plenty to do in this space.

Vibha R: Okay. Thank you.

Moderator: Thanks, Vibha. So, for the last question, let's have Saion Mukherjee back.

Saion Mukherjee: Yes. Thank you. Thank you for the follow-up. Just two quick questions. Firstly, on the API piece, you mentioned some that it's kind of coming back. So how should we think about that? And what is really driving is it the cephalosporin piece? And if you can just highlight the dynamics there? And what are your expectations going forward on API?

Nilesh Gupta: Sure, so it's actually been depressed for the last two years, and that's the part that's coming back. So we actually see that bounce back, but that's primarily

in the cephalosporins. Our big categories are the anti-TB products and cephalosporins. So that's where that would come from.

We definitely see it picking up, not across the board, but certainly in certain products, we see it picking up. I think it's come back to that level. It's kind of going to stay at this level. It's not going to keep increasing from this level. That increase will come from new products. And we have a portfolio of new products within our API portfolio.

We'd appreciate that PenG prices are still rolling at a pretty high over the last few, several quarters.

Saion Mukherjee: Right, right. And the last one, Vinita, on Europe, Fostair, we have seen some pickup in UK, now you've got approval in Germany. So, what are your peak sales expectation? And when you expect that to achieve?

Vinita Gupta: So we are already doing pretty well in the UK. And Germany actually launched in the last month. And the other countries through our partners in Italy and other countries, we've also begun launching the product. So, it's well on its way next year fiscal year '25 should be a peak year for Fostair.

Saion Mukherjee: Okay, and can you share what kind of peak sales you're expecting in Europe?

Vinita Gupta: I don't think we have shared like product wise sales, but suffice to say that it's going to be a good percentage of our revenues in Europe.

Saion Mukherjee: So, do you think that it would be like meaningful number from where we are today in FY '25?

Vinita Gupta: Yes.

Saion Mukherjee: Okay, okay. Thank you.

Moderator: Thank you very much to all the participants for being so patient. I now hand the conference over to the management for closing comments. Over to you.

Vinita Gupta: Thank you all for your very thoughtful questions. Hopefully, we were able to respond to majority of them. Any that we haven't been able to, we'll certainly catch up offline. We are very energized with the start of this fiscal year, as you can see, and look forward to continue to execute, especially given the opportunities that we have now in the next couple of quarters. And again,

catch up with you in the next quarter, hopefully, with a better set of numbers. Thank you again.

Moderator: Thank you very 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.