"Lupin Limited Q1 FY2027 Earnings Conference Call"

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Moderator: Hello, good evening, and welcome to Lupin Limited Q1FY27 Earnings Conference Call. Thank you for your participation in the call today. 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 also note that this conference is being recorded. I now hand over the conference to the management. Thank you, and over to you, ma'am.

Vinita Gupta: Good afternoon, friends. I'm very pleased to welcome you to our Q1FY27 earnings call. I have with me our MD, Nilesh; and our CFO, Ramesh; and our Head of Investor Relations, Ravi. We look forward to sharing with you our highlights for the quarter as well as the outlook for FY27. We are delighted to announce a record quarter with total revenues from operations and EBITDA exceeding INR 8,000 crores and INR 2,400 crores, respectively, for the first time in our history. This quarter also marks a record 16th consecutive quarter of YoY growth for the company.

While the U.S. has obviously had an exceptional contribution to this performance, I would like to highlight that the ex-U.S. organic revenue growth for the company has been a strong 20% plus YoY and a strong double-digit growth in all our key markets, including India, Other Developed Markets, and Other Emerging Markets. This geographically diversified business model combined with our unwavering focus on operational excellence creates a sustainable foundation for future growth, even as we navigate the increased competition in some of our key generic products in the U.S. this year.

Turning to individual business segments. Our U.S. business sustained its positive momentum and delivered another quarter of robust sales performance. While we benefited from the higher volumes in base portfolio and growth in products like Tolvaptan, this was offset by increased competition in products like Mirabegron. For the full year, we expect the U.S. business to be in the USD 1.1 billion to USD 1.2 billion range, aided by growth in base business, our injectable launches, and contribution from Pegfilgrastim offsetting the additional competition in products like Mirabegron and Tolvaptan during the year.

Going ahead, we remain focused on doubling the share of our complex products in our U.S. business, led by respiratory and complex injectables, and augmented by biosimilars. In the next three years, we expect to launch 50 plus products in the U.S. with 10 exclusive first-to-files, five biosimilars, as well as two to three 505(b)(2)s. We are planning to file more than 15 products this year, including at least seven in the Respiratory segment. We believe that all these initiatives should help in the U.S. getting back to its growth trajectory from FY28 onwards.

Coming to India, our India business has grown 13.9% YoY in the quarter with the core prescription business growing 15.1%, representing a 1.1x growth against IPM. Volume growth was strong at 6.1% during the quarter. The Chronic segment accounts for around 67% of our portfolio, up from around 65% in FY26, and we have set ourselves a target to increase the share to 70% in the next five years.

Most of our key therapy areas outperformed the respective market growth with Anti-Diabetes segment and Cardiac segment growing 1.8x and 1.2x the category growth. I would specifically like to mention Diabetes segment, which grew at 31.8% YoY, a second consecutive quarter of 20% plus growth, led by market leadership in Huminsulin® and successful launch of Semaglutide injection. This segment is poised for continued healthy growth with the expected launch of vial and oral dosage forms of Semaglutide in the second half of this fiscal year.

We remain confident that our India formulations business will continue to outperform IPM by 1.2x to 1.3x, supported by our strong India prescription sales force of nearly 11,300 people and pipeline of more than 80 new product launches over the coming years. We have set ourselves a target of novel proprietary products contributing one third of our India revenues in the next 10-year timeframe. This innovative portfolio for India will come from in-house development as well as in-licensed products, leveraging our strong partnership track record, brand building, development, regulatory and clinical capabilities.

Our Other Developed Markets, Europe, Canada, and Australia, accounted for 14% of our revenues in this quarter, up from 11% in FY26. Sales grew 48% YoY in the quarter. Our European business continued a strong momentum with 83% growth YoY. We believe that we are under-indexed in Europe and have set a clear pathway to grow this business with our complex generics, biosimilars portfolio, as well as specialty acquisitions, such as VISUfarma.

Emerging Markets delivered an impressive 52% YoY growth, led by Brazil, South Africa, and Philippines. Brazil continued the strong momentum of the last four quarters, growing 117% YoY in local currency during Q1, driven by successful commercialization of Dapagliflozin and launch of Empagliflozin. As mentioned earlier, we are starting to establish a presence in the diabetes metabolic space in the emerging markets, with Dapagliflozin serving as a strong start, and the launch of Empagliflozin in Brazil and South Africa, as well as Semaglutide in South Africa later this year.

Turning to R&D, our spend was 7.4% of sales this quarter, with continued focus on complex and specialty platforms. We have over 50 active products in the pipeline with near-term emphasis on respiratory, complex injectables, and biosimilars. We've also evolved a strong 505(b)(2) pipeline in the last couple of years, and we'll start seeing product launches this fiscal year and ramping up in the next two years. We're also strengthening our India innovation portfolio through both in-house development and in-licensing of late-stage assets, as I mentioned earlier.

Switching to compliance, we received EIRs for Ankleshwar and Somerset with VAI status from U.S. FDA for both sites during the quarter. With regards to Pithampur Unit II facility, we have submitted our responses and remain on track with our remediation efforts. We are fully committed to maintaining the highest standards of quality and compliance across all our sites globally.

In conclusion, while we have started the year on a strong note, as indicated earlier, we anticipate some moderation in performance during the remainder of the year, especially in the U.S. from increased competitive intensity on our two major products. We are closely monitoring the potential headwinds from an uncertain geopolitical environment as well.

We would like to reiterate our earlier guidance of high single-digit revenue growth for the organization with EBITDA margins of around 25% during the year.

Before I hand it over to Ramesh, I would like to say that we are optimistic on our future growth trajectory. We are on the path to strengthen our diversified business model, while we continue to evolve our business into higher barrier generics, branded, as well as innovative products.

Ramesh, over to you.

Ramesh Swaminathan: Thank you Vinita. Friends, I welcome you all to our Q1FY27 earnings call.

I'm happy to report another record quarter of earnings with total revenue from operations growing 32% YoY to INR 8,277 crores, and EBITDA excluding forex and other income growing at strong 50% YoY to INR 2,464 crores. This marks the 16th consecutive quarter of growth for the company.

What is heartening is that the growth has been diversified and robust across our major geographies, be it the U.S., which grew by 43% YoY; India prescriptions, which grew 15.1% YoY; Other Developed Markets, which grew 48%; Emerging Markets grew 52% YoY; and our GIB business, which grew 40% YoY during the quarter. As Vinita mentioned, our organic growth ex-U.S. was a strong 20% plus YoY during, bearing testimony to the resilience of our business model.

U.S Business

During the quarter, the U.S. business recorded sales of USD 366 million, 30% higher YoY in constant currency terms. This growth has been driven by higher volumes in base business, offset by additional competition in key products like Mirabegron. Whilst we continue to benefit from our differentiated strategy on focusing on complex products, as indicated in our earlier interactions, the overall sales in the U.S. will be impacted by competition in key products like Mirabegron and Tolvaptan this year. However, we anticipate the business to revert to its growth trajectory from FY28 largely led by a rich pipeline of products including exclusive first-to-files, biosimilars and 505(b)(2) products. In addition, we have an attractive pipeline of more than 60 products in injectables and respiratory products currently under development which will augment our complex portfolio going ahead.

India Region

During the quarter, the India business recorded sales of INR 2,380 crores, growing 13.9% YoY. I would like to highlight that the core prescription business grew 15.1% YoY as against IPM growth of 13.5%, translating to 1.1x IPM growth. This is offset by lower tender sales in our GIB business in India. Key segments like Diabetes and Cardiology handsomely outperformed their category growth at 1.8x and 1.2x respectively. This is offset by lower growth in Respiratory segment which grew 6.9% as against category growth of 11.3%.

Volume growth has been a healthy 6.1% during the year, and the chronic share in the mix has increased to around 67% from around 65% in FY26. The share of in-licensed products in this quarter is around 6%, similar to the FY26 levels. We have launched around seven products in Q1FY27 and plan to launch about 20 products in FY27, vis-a-visa 15 products which we have launched in FY26.

We remain confident that our India Formulations business will continue to outperform IPM by 1.2x - 1.3x to supported by a strong sales force of more than 11,000 people and pipeline of more than 80 new product launches over the coming years including innovation in-house and in-licensed products.

Other Developed Markets

For the quarter, our Other Developed Markets, Europe, Canada, and Australia recorded sales of INR 1,149 crores growing 48% YoY and accounting for 14% of our total sales, an increase from 11% in FY26.

I would like to highlight that we have begun consolidating VISUfarma in our financials from this quarter. As Vinita mentioned, we are focusing on various strategic initiatives to grow our business in this region, especially in Europe going ahead.

Emerging markets

For the quarter, emerging markets recorded sales of INR 990 crores, delivering an impressive 52% YoY growth led by markets in Brazil, South Africa, and Philippines. Brazil in particular maintained strong momentum post the turnaround of the last few quarters, growing 117% YoY in local currency, driven by successful commercialization of Dapagliflozin.

P&L

Going on to the P&L.

Other Operating Income

Other Operating Income at INR 60 crores as against INR 105 crores in Q1FY26, has decreased 43% YoY. This decrease is primarily on account of lower export benefits from the PLI schemes during the quarter.

Gross Margins

Coming to the profitability of Gross Margins, the upward trajectory continues. This quarter was at 74.6% up from 71.3% in Q1FY26 last year. This 330basis points YoY improvement is driven by multiple factors, which includes better product mix, higher profitability in India, increased volumes, cost improvements and efficiencies which we have undertaken over the last several quarters.

Employee Benefit Expenses

For the quarter, Employee Benefit Expenses stood at INR 1,383 crores, increasing 28% YoY from INR 1,083 crores in Q1FY26, translating to 16.8% of sales versus 17.6% last year.

This change is largely attributable to higher costs due to regular annual increments and business growth during the period.

Manufacturing and other expenses

Q1FY27 Manufacturing and Other expenses came in at INR 2,341 crores, which translates to approximately 28.5% of sales as compared to 28.7% of sales in Q1 last year. The expenses were higher mainly due to higher volumes in normal course of the business, higher SG&A expenses on account of field force expansion, license fee payments and a part of settlement agreements.

R&D

R&D at INR 608 crores is 7.4% of sales in Q1FY27, as compared to INR 498 crores at 8.1% of sales in Q1FY26. For the full-year, R&D is expected to be around 8%.

EBITDA

EBITDA excluding forex and other income during the quarter was INR 2,464 crores vis-a-vis INR 1,641 crores in the same period last year, an increase of 50% YoY. Margins were 30% vis-a-vis 26.6% last year in the same period, an increase of 340 basis points over the last year. For the full year, as indicated by Vinita, we expect EBITDA margins to be around the 25% mark.

Depreciation

Depreciation & amortization at INR 453 crores is compared to INR 299 crores in corresponding quarter last year. This increase is due to higher amortization of settlement agreements.

ETR

The effective tax rate stood at 29.8% for the quarter. For the full-year, however, we expect it to be in the region of 27% - 28%.

Balance sheet

Operating Working Capital

The Operating Working Capital was INR 8,260 crores as of 30 June '26 as compared to INR 7,132 crores as of 31 March '26, which translates to 90 days of net working capital as compared to 87 days recorded earlier.

Net Cash

Net cash stood at INR 2,831 crores as of 30 June vis-a-vis INR 4,636 crores as of 31 March quarter, largely due to closure of our VISUfarma acquisition. Whilst we focus on increased cash generation for our business, we'd like to highlight that we continue to explore strategic allocation of our capital to ensure the long-term mission of the company, including on the speciality front.

ROCE

ROCE for the company translates to 29.5% vis-a-vis 28.4% as at end of FY26.

ESG

On the ESG front, Lupin continues to advance steadily towards its 2030 sustainability goals, achieving approximately 41% reduction in greenhouse gas emissions, and 45% water recycling as of FY26. Our efforts have been recognized externally through inclusion in the TIME World's Most Sustainable Companies 2026 List for the first time.

With this, we'll open the floor for discussions.

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

The first question is from Damayanti Kerai.

Damayanti Kerai: My first question is on your opening remarks where you mentioned that U.S. sales should be back on growth trajectory starting FY28. So just want to understand, this growth will be on the base of USD 1.1 billion to USD 1.2 billion number, which you mentioned for FY27, or how should we understand this part?

Vinita Gupta: That's right. Over the FY27 base.

Damayanti Kerai: My second question is, if you can update us on some of the key launches or key products in injectables and respiratory space, which will be meaningful from your U.S. sales perspective?

Vinita Gupta: So, there are multiple products in the biosimilars, injectables, and respiratory front over the next couple of years.

In FY27 itself, we have yet to launch Pegfilgrastim that is going to be an H2 product for us. We expect it to contribute very nicely into the second half. Then we have a 505(b)(2) Dalbavancin injectable that is going to be a good size product for ourselves as well. And nasal sprays like Fluticasone nasal

spray, as well as injectables, Sugammadex, Epinephrine, Raltegravir, where we have exclusive first-to-file, Eribulin injection, which is all FY27.

Then FY28, full-year impact of Pegfilgrastim. We have Diazepam nasal spray, Epinephrine nasal spray, as well as Apixaban 505(b)(2). That is starting to look like a material opportunity for us. We're still sizing it up, but it is looking fairly interesting for us. Then iron sucrose injectable and Saxenda®. We have Ivacaftor exclusive first-to-file, Midazolam nasal spray, and they're just a few of the products. We have other nasal sprays as well as injectables in the pipeline that we'll expect to bring to market in FY28.

And then I'd say that in FY29, we should have more biosimilars, Aflibercept, Pegfilgrastim on body injector. Dulera is expected. Hopefully we can get it in FY28, but if not, for certain in FY29 on the market. And depending on what transpires from a P4 standpoint, we would expect Spiriva Respimat®. We've made good progress on that front; we expect to file it in this fiscal year. We should, subject to what happens with the brand, the P4, we could potentially be in the market on the Respimat front as well in FY29.

Damayanti Kerai: Last question is, when you look at the Tiotropium market share, it has been hovering around mid-30s. So, do you have room to improve it further? And if you can talk a bit about your progress in the incremental channels for this product?

Vinita Gupta: It's kind of settled at that 38% level. And there is a good balance between what the brand has in terms of share and what we have in terms of market share. So, at this point, it should hover around that level.

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

Shyam Srinivasan: Just trying to do math on your U.S. guidance. We did USD 366 million this quarter. You talked about USD 1.1 billion to USD 1.2 billion for the full year. So that brings us like roughly USD 100 million lower per quarter, in some of the quarters, right? So, if I'm doing simple math, then USD 250 million and USD 280 million roughly, right? What is that big step-down? Is it both the top two products that will likely see the step-down, or is there an element of conservatism built into the kind of step-down? Just want to get some qualitative sense of why despite a very strong Q1, how are we looking at it?

Vinita Gupta: In Q1, you don't have any additional competition on Tolvaptan. And from Q2 onwards, you will start seeing the impact of Apotex and Teva. We also expect in September, we could potentially have one more entrant. We expect to be a four-player market with Tolvaptan. And we expect the market to grow as well for the molecule, given that it is still 40% generic conversion so far. But given the additional competition, we expect pricing to come down, and obviously also some share re-distribution. So, we expect Tolvaptan to come down over the next couple of quarters. Mirabegron has already seen pressure in the first quarter, and we expect that to be a full quarter impact from Q2 onwards. We expect revenues to be anywhere between USD 250 million to USD 280 million a quarter over the next couple of quarters.

Shyam Srinivasan: When I look at your full-year margin guidance of about 25% and we did the gross margins of 75% for the current quarter, right? So, what's a more normalized gross margin, please?

Ramesh Swaminathan: It is really going to be a function of how much of Tolvaptan sales and at what realization, the kind of competition that you see out there. And more importantly, the impact of price increases that we have seen in the recent past; post the cost increase that is because of the geopolitical tensions around.

So, the first quarter was not so hugely impacted because of the fact that we had inventories that we carried forward, but going forward, we will have to take that into account. So, I think we are being a little more cautious when you speak about the fact that the EBITDA margins would be in the range of 24% to 25%. And obviously, this would be, as a reduction on the gross margins front as well.

Moderator: The next question is from Neha Manpuria.

Neha Manpuria: In Tolvaptan, we have seen a QoQ increase in market share. Would that be a fair assumption?

Vinita Gupta: Yes.

Neha Manpuria: I think in one of your previous call, you'd mentioned that despite additional competition coming through, we should be able to defend our market share in Tolvaptan. Do you see that dynamic playing out given that we've been able to gain share over the last few quarters?

Vinita Gupta: Yes. We would expect the market share tail to be longer, because of the fact that it's a specialty pharmacy product as well as our REMS program. But we obviously will have to give some share as well to the additional entrants.

Neha Manpuria: In Apixaban, how should we think about the opportunity? You mentioned you're still sizing it up, but how should we think about the 505(b)(2) launch and our ability to take market share in case we launch it in FY28?

Vinita Gupta: We are looking at the different channels for the product. It's a very large brand, which makes it a very interesting opportunity. But given the time we have, prior to the other generics entering the market in FY29, we believe that a very targeted approach around a few channels is going to serve us well. So, we are looking at ways and means of entering, a few of the larger channels through our national accounts' efforts, as well as some incremental commercial efforts, to be able to get strong access.

Neha Manpuria: Do you think this should be as large as probably, Mirabegron and Tolvaptan was for us? Could this be as large in your view?

Vinita Gupta: It could potentially get there.

Neha Manpuria: Last question on, biosimilars. Let's take a three-year timeframe because you have a couple of launches coming in FY29, how big can the biosimilars piece be for us here as well as in Europe put together?

Vinita Gupta: Put together, it's a material opportunity for us. The U.S. itself, of course, we have to deliver this year, but it's looking like a very interesting opportunity with Pegfilgrastim. Ranibizumab, we'll have to convert the market. I mean, the market has gone into the other products. I think a little bit of a smaller opportunity compared to Pegfilgrastim, but Ranibizumab looks like a big opportunity for us in Europe, in a few countries direct and also through our partnerships with Sandoz as well as others.

Now, with the VISUfarma footprint that we have across the ophthalmology call point, we're going to leverage that as well for Ranibizumab. And then we have Aflibercept coming in FY29, and the Pegfilgrastim OBI. In FY30, calendar year '29, we have Etanercept. So, I think we are looking at biosimilars ramping up in the next three years to a couple of hundred million dollars scale business across these key markets.

Moderator: The next question is from Soorya Patra.

Soorya Patra: My first question is on the respiratory portfolio. How big is the respiratory portfolio contribution to the overall business for Lupin right now? In terms of the U.S. business, what would be its share currently?

Vinita Gupta: In the base business, I'm just going by memory here, it's over 20% right now, Tiotropium, Albuterol as well as Xopenex®. So, a little bit more than 20% even.

And as we look at our pipeline, we have Dulera® that is filed. We have multiple products that we are now making progress on like, Respimat, we have made significant progress over the last quarter, and we are in a position to file this fiscal year. We also have been successful with a pivotal PK on Breo®. So very pleased to get the Ellipta franchise also started from a pipeline perspective, and we would expect to file the ANDA later this fiscal year.

We have green propellants, the Luforbec® new propellant filed in Europe in the last quarter in fact, and multiple pipeline programs also making progress for Europe. So really pleased with the progress now that we are making on the respiratory pipeline, with MDIs, DPIs, Respimat, Ellipta, as well as green propellants.

Soorya Patra: From the Albuterol side, for which the market share, has to some extent subsided from the level of 19% - 20% to 16% currently, and possibly we have already reached the peak potential of Tiotropium. So here, in the mid-term, till the time that the pipeline products are getting launched in the U.S., is it fair to believe that the respiratory portfolio in the U.S. is likely to remain flattish or kind of moderating like that?

Vinita Gupta: This is hard to predict for certain. But right now, the Albuterol market has stabilized. It has the 16% share, and the relative positions of competition are kind of stabilized based on the supply situations from the different competitors.

On Tiotropium, we know how difficult it has been for us. We haven't really heard of any imminent approvals and launches. So, we would expect that the baseline should be stable as Dulera®, our nasal spray products in the next year, and then the new products, Respimat, as well as others come to market.

Soorya Patra: My next question is on the Europe business, which has been doing great for us, and that is visible even in this quarter. But I was just going through the kind of a higher rebate policy initiated by Germany, wherein they are kind of doubling the rebate requirement. What would be your reading about either profitability or pricing pressure what we can see in the European market? Or let's say, if it is Germany, then even if we restrict that policy to Germany, then what implication that the overall Europe portfolio can see because of this?

Vinita Gupta: It's very interesting, the dynamics in all of the European countries that we are realizing. And even in Germany, on the one side, you see the increase in rebate on a part of our portfolio, but in others, for example, in our biosimilars, in particular for Ranibizumab and Aflibercept, we are finding that it's not part of the AOK tenders anymore. So, it becomes a nice, branded opportunity. Overall, we are seeing all the major European markets really struggling with the overall healthcare budgets, the overall drug spends budgets, and they are struggling to really bring more innovative products into the fold and not making enough products available for unmet needs for patients.

We are starting to see, like, in countries like France, we have recently noticed that they are really doubling down on biosimilars, just given how important the biologics LOE is. Right now, it's like USD 100 plus billion worth of biosimilars that go off patent over the next five to 10 years. So, more incentives for substitution of biosimilars that we have seen to be able to reduce some of the drug spend so that they can make room for innovative products.

And I think if that model works for France, we will see very soon the other countries following a similar model to be able to afford innovation, while making the generic side and the biosimilar side of the business more substitutable to be able to get efficient access to medicines. We are very optimistic, very hopeful that Europe is going to increasingly become a more important geography for Lupin for certain, just given our portfolio of respiratory products, biosimilars overall, as well as the ophthalmology biosimilars, as well as the specialty portfolio. We have tremendous headroom to be able to build in Europe.

Soorya Patra: Just last one question from my side regarding the biosimilars. Two points specifically here. How sizable are these two opportunities, first two product opportunity in the U.S., for us, because Pegfilgrastim or even Ranibizumab, if you consider both are kind of a partner product, and the prices for this product, for biosimilar prices has already corrected to the tune of 85% to 90%. So, considering that, how sizable this could be?

And secondly, given the sharp price erosion that has happened already in the U.S. market, how is the European product prices there in biosimilars compared to that of the U.S.?

Vinita Gupta: So even with Pegfilgrastim, as I mentioned earlier also the last couple of quarters, we've been pleasantly surprised with the opportunity that we see right now. And of course, we'll want to deliver that in this fiscal year to be able to gain that confidence operationally. But as we look at our partner's

forecast and what we can do in the current fiscal year, it's a really good size opportunity for Lupin. As I mentioned, I will not size up each and every product, but if I look at the next three years between U.S. and Europe with these three products or so, we have a couple of hundred million dollars worth of opportunity on the biosimilars front.

Soorya Patra: And price difference in U.S. and Europe?

Vinita Gupta: In Europe, the pricing on our products is fairly stable. And like I mentioned, we're also starting to see new developments, like in Germany, these products are not part of tenders, so more of a branded opportunity on the ophthalmology front. In France, new measures that will likely enhance biosimilar adoption and ease market access for us, all of which gives us this optimism on the biosimilars front.

Moderator: The next question is from Bino Pathiparampil.

Bino Pathiparampil: Just a follow-up question on couple of products, which you mentioned. You mentioned the first-to-file exclusivity in FY27. I didn't get the name, but is that a sole exclusivity?

Vinita Gupta: On Raltegravir, yes, I mentioned that.

Bino Pathiparampil: Second one in FY28, which is the one you mentioned as sole exclusivity?

Vinita Gupta: I mentioned Diazepam, Epinephrine that is two nasal sprays, Ivacaftor is another. And yes, those would be the main ones. Suflave® is another exclusive first-to-file next year.

Bino Pathiparampil: Last question on Spiriva Respimat®. How is the market compared to the DPI?

Vinita Gupta: It's moved more towards the Respimat.

Bino Pathiparampil: If you could give some rough size idea?

Vinita Gupta: We'll get back to you with that. I don't have the exact numbers.

Moderator: The next question is from Kunal Dhamesha.

Kunal Dhamesha: The first question is on the India business that you shared, that we are planning to derive one-third of the revenue from innovative products. So, can you elaborate more on this strategy, what would be the kind of required investment here, both from balance sheet and P&L perspective? And the usual impression is such in-licensing deals are not very accretive to profitability, right? So, what are we going to do differently? And from therapy perspective, do we stick to our key therapies of cardiac, anti-diabetic, or we look at a more high-growth therapies like oncology?

Nilesh Gupta: So, I think there's three avenues of proprietary products. One is our internal pipeline. So, we're building those internally. Another is in-licensing deals, as you talked. And the other most important and what will be the biggest will be pure innovative NCEs that we would bring to market, products like Bofanglutide that we announced a little while ago, which is now in the clinical development path, and in the next couple of years, we should be able to bring to market.

So, we've allocated the capital for this. It's purely India. It's not that expensive from overall licensing or a development perspective. Obviously, you need to have the entire suite of capabilities. So, you do need to have the ability to assess a new chemical entity at an early stage, do the clinical development and bring it to market. And in a market like India, how do you build ability to do, over a period of time, 30, 40, 50 assets at a time.

The goal of USD 1 billion or one-third of our business to come from innovative products is an aspiration for the next 10 years. But I think if you break it down, it basically means to be able to do 10 to 15 products every year. I think it's coming together quite well. So, in the next three years, we should start bringing those products to market and really build that pipeline.

Obviously, key interest would be in our key therapy area, so which are products in respiratory, cardiology and diabetes. From an innovation perspective, obviously, 50% of what you would see as assets would be in areas like oncology, where we're not strong. Then we would cherry pick and we would pick assets that we feel can be really first-in-class, so that it can make a real difference in the market. We've started the journey. I think we've started it with putting strong capability together as well. And we'd love to keep updating you as the pipeline develops.

Kunal Dhamesha: You are suggesting like 80 launches in India in the next three years, right? So how many of that you think would be from this market?

Nilesh Gupta: So, over a period of the next 10 years, we're looking at 60 to 70 launches of the innovative products. In the next three years, a very small fraction, I would say not even three, four of these would be truly innovative products.

Kunal Dhamesha: In terms of profitability, would it be similar to our India business whenever it scales up, or how should we think in the longer run?

Nilesh Gupta: Certainly similar if not better. So, we would expect that. I think you already pointed to how much is the actual burn on the clinical trials , but I think the entire model looks really good. And in the next few years, you'll start seeing positive returns coming from it.

Kunal Dhamesha: Given that we have now established track record of selling both DPI & MDI products in U.S., how is it helping us in terms of clearing or like developing the next phase of respiratory products in terms of development cycles in your view? How the development cycles are shrinking and what are some of the learnings, which would help you bring this next wave of products to the market efficiently?

Vinita Gupta: I'd say that in the different platforms, the complexities are different. On the MDI front, it's going to be a significant year of filings on the respiratory MDI products. I'd say on the Ellipta® platform, that was likely our most challenging platform. We've been working on it for multiple years and I'm very pleased to finally be able to get a positive PK on the first product.

Now, the next major is getting Trelegy® right which our team is working upon and they're going to apply the learnings they have from Breo® onto that product.

And then on the Spiriva front, on the Respimat Spiriva, there was more of a device challenge that we faced & that now that we have cleared it and we'll file the product this year. The follow-on products become easier for us. So, I'd say different level of complexity across the different platforms, but a lot of learnings over the last couple of years that the team will leverage to be able to expedite the filings as well as potential approvals. Given that these products are either CGT or have no competition in the marketplace, the FDA is also looking to expedite these approvals. So, I'm going to look forward to leveraging that.

In addition to that, a number of these products are out of India, some out of our facility in Coral Springs. We'll also want to leverage the Coral Springs domestic manufacturing in the U.S. for expedited review of these products that the administration is focused on to get more onshoring of products in the U.S.

Kunal Dhamesha: Just one aspect of this, let's say, if you have an MDI line for one product, can the capacity become fungible for another MDI, or it does not?

Vinita Gupta: It does.

Kunal Dhamesha: On the Apixaban 505(b)(2). From here, what are the key monitorables for you? And what's the duration advantage that we will have vis-a-vis the generics, which has slated to enter the early part of FY29, I believe?

Vinita Gupta: As I mentioned, we are sizing it up, but like material brands, so one first monitorable thing that one can track is the approval. We have a goal date of September. We are hoping that we get approval in September, and then simultaneously we're building up launch quantities. And we expect to start having material commercial quantities start in January '27 calendar year, and we would expect somewhere in the summer that we should launch and hopefully get 10 to 12 months before others enter.

Kunal Dhamesha: Can you share, which plant is it filed from?

Vinita Gupta: It's Somerset, that's been cleared recently.

Moderator: The next question is from Tushar Manudhane.

Tushar Manudhane: In the opening remarks, you alluded to Fluticasone nasal spray. What dosages have you filed? And like where are we in terms of the approval process?

Vinita Gupta: We filed both the Rx as well as OTC. We would expect the Rx approval to come in this year and OTC in FY28.

Tushar Manudhane: All the formulation as well as API being manufactured in-house, or how is it?

Vinita Gupta: The formulation is all in-house. The API is not.

Tushar Manudhane: Device is also in-house?

Vinita Gupta: No we chose the device, of course, through a device manufacturer.

Tushar Manudhane: You referred to Apixaban 505(b) (2) right? If you could just qualitatively help understand what's the differentiation this product is going to bring compared to what the innovator's product?

Vinita Gupta: We'll maybe share that closer to the launch date. We're sizing up the opportunity, and we'll be in a better position to share that over the next couple of quarters.

Tushar Manudhane: Just trying to understand the value addition compared to the innovator product, not so much like in terms of pricing. It was more in terms of the value addition compared to an innovator product?

Vinita Gupta: It definitely would be an unmet need for patients that we've targeted. But let us come back to you with thoughts around it over the next couple of quarters.

Moderator: We can take the next question from Vivek Agarwal.

Vivek Agarwal: Couple of questions on the cost base. If you look your staff cost and other expenses have gone up meaningfully. So, just if you can help us understand, how to look at these lines going forward, and what is driving these cost lines significantly?

Ramesh Swaminathan: The cost lines are essentially because of increments, then based on the needs of business, including India region, we have also been recruiting people. And there's also an Fx impact, at least, vis-à-vis the previous year.

Vivek Agarwal: Is it fair to understand right, before you launch a major product that is Apixaban and in between a couple of major products, you are seeing incremental competition, there may be a few quarters where your EBITDA margin can fall even below 20%?

Ramesh Swaminathan: There will be volatility between quarters, for sure. The magnitude is something that we can't actually speak about at this stage. But we would also do well to understand that our R&D expenditure is at least ahead above the competition, firstly. And secondly, we also have the impact of adjacencies and so on, which have been captured. They're still evolving. Some of them are still making losses, though, of course, I think it will come down over time.

Next year, for example, we believe the Diagnostics business will do very well. It will be break-even, for sure. And I would say the same thing for other businesses. Our Digital business is evolving extremely well. You could say that for the OTC business and CDMO as well. But I think you would do well to remember that all of these are at this stage loss making and therefore is impacting EBITDA margins and of course, our overall EPS at this stage. But clearly, that would be a thing of the past in quarters to come.

Vivek Agarwal: Is it possible for you to quantify what kind of the losses in terms of percentage hit on EBITDA margin these adjacencies are contributing at this point of time?

Ramesh Swaminathan: Overall about 1% - 1.5%.

Vivek Agarwal: One product specific question I have. You have a one product, one FTF that is Xywav®. So, is it a FY29, FY30 type of product, or is it like a FY30 or beyond?

Vinita Gupta: It's a FY33 product for us.

Moderator: We can take the next question from Saurabh Kapadia.

Saurabh Kapadia: Just one question on the Other Developed market and EMEA. What could be the sustainable growth in this market over the next couple of years?

And secondly, with the kind of growth we have seen, how the profitability or the margins in the key market have moved over the last three - four quarters?

Vinita Gupta: We are looking at potentially double-digit growth, in some years., higher than others, but anywhere between 10% to 20% over the next couple of years. And the margins just given the scale of the business is growing. We've been subscale so far. And with the additional portfolio, as well as the expansion with the pipeline, we expect margins to continue to expand as well.

Saurabh Kapadia: Do we need incremental investment to be made in any of the geography or any potential inorganic opportunity, which we could seek in any of these specific countries?

Vinita Gupta: We expect to really maximize the biosimilars business. We are going to make a small, but commercial investment, in particular in the U.S., even for the 505(b) (2) of Apixaban. And our strategy on the 505(b)(2) front, because we have other products that we have targeted as well, we'll likely make a small commercial investment.

Moderator: We can take the next question from Chintan Sheth.

Chintan Sheth: I have a question on the U.S. side of the business where we have put out the numbers in terms of upcoming pipeline of 50 FTFs, 21 exclusive ones. If you can cumulatively provide some indication on the market size of those, and how should one look at monetizing those over the course of next three to five years? You've explained a few of the products already, but if you can cumulatively help us understand how would those numbers can contribute to our incremental revenue in the U.S. markets.

Vinita Gupta: Perhaps what we can do is get back to you offline to go through the overall brand revenues and the relative products where we have limited competition. Overall, we are looking at our portfolio from the complex generics doubling over the next three to five years. That along with the fact that we believe with the pipeline we have, we should be able to grow our business in the next three to five years. With the inherent growth out of this pipeline, plus the fact that we are increasing from a complexity standpoint. We are looking at a potential expansion in margins.

Of course, we'll make investments as well, as I mentioned, in maximizing these opportunities. But maybe our team can get back to you offline on looking at the overall market size and the like.

Chintan Sheth: On the EMEA side, and I believe the growth is coming because of the VISUfarma acquisition for last four quarters. Base of Q2 kind of bakes in the VISUfarma. How should one look at the growth in that piece, EMEA business going forward?

Vinita Gupta: We're looking at anywhere from 10% to 20% level in Europe. So, splitting out South Africa separately is a little bit lower. Just given the scale we are at. With the pipeline portfolio that we have and the opportunities, Europe should grow at that 10%-20% to level.

Chintan Sheth: Any colour on the ROW market growth.

Vinita Gupta: Also, double-digit growth.

Chintan Sheth: To continue?

Vinita Gupta: Yes.

Moderator: Thank you very much. I now hand the conference over to the management for their closing comments.

Vinita Gupta: Thank you, friends, for all your questions, and hopefully, we've been able to answer majority of them, but if not, the team will connect and clarify any open questions you have. As I mentioned, we are optimistic about a near-term opportunity as well as long-term opportunity. In the near-term, to be able to navigate our near-term challenges with the opportunities we have from a portfolio perspective, evolving in areas that we've invested for the last many years.

In the longer-term, as Nilesh mentioned also, as we evolve innovation, innovation in India, innovation in our specialty business in Europe as well as the U.S., we look forward to delivering long-term growth as well as return for all our stakeholders. Thank you again, and we look forward to connecting with you in the future.

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