May 25, 2022

**BSE Limited**
Department of Corporate Services,
P. J. Towers,
Dalal Street,
**MUMBAI - 400 001.**

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

***Dear Sir/Madam,***

**Transcript of Q4 FY2022 Investor Meet/Earnings Conference Call.**

Pursuant to Regulation 30(2) read with Schedule III Part A Para A(15)(b) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Q4 FY2022 Investor Meet/Earnings Conference Call held on Thursday, May 19, 2022.

The above is for your information and dissemination.

Thanking you,

**For LUPIN LIMITED**

LUPIN LIMITED INDIA MUMBAI

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

**Encl.: a/a**

# “Lupin Limited Q4 FY2022 Investor Meet / Earnings Conference Call”

**May 19, 2022**

**MANAGEMENT:**

- **MS. VINITA GUPTA – CEO, LUPIN LIMITED**
- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
- **MR. RAMESH SWAMINATHAN - EXECUTIVE DIRECTOR, GLOBAL CFO AND HEAD CORPORATE AFFAIRS, LUPIN LIMITED**

**Ramesh Swaminathan:** Now, it's been four years since I last met with investors from Lupin. So I was really looking forward to meeting with you today.

I hope you and your relatives, your family have been keeping safe during this time. The last couple of years have been pretty bad for a lot of families. I hope you have been doing good.

Of course, I have been in touch with people about our performance. You've been posing questions to me from time to time. And of course, we have had our regular investor calls like every quarter and you have already supported us, guided us, assisted us and we should be looking at things and so on. Thank you for that.

Again, coming back to the current year performance, happy to take you through our quarterly performance as well as our results for the year itself. It's a smaller crowd out here, but I'm sure there are lot of people who are on the call itself, who would potentially be asking us questions because as per the SEBI regulation, I think we need to be live for the rest of the community to interact with us. So I really would be looking forward to questions from those people who are online, so to speak. And I'm happy to take this again.

So, we'll begin with the presentation. So, this is our strategic vision. Next slide, please. Go on to the slide after that. This is our strategic vision for us as a company: a global pharma company focused on core growth platforms. As you recognize, we have done extremely well in India over time.

As I listened to a lot of you, you have also been telling me that you should really be focusing on India. And just about a few minutes ago, it was very surprising because sort of people are telling me, as I was listening to them, that India is -- your valuation has been captured in India per se, and the rest of the business has not actually been valued. And to that extent, it is surprising in some ways. I'm sure there are going to be a lot of questions about some of the parts and how we could take this forward, so they're talking to me about that.

And so we are looking at India very, very seriously, both organic and inorganic growth. And as we've recognized, we've done a stupendous job out here. And we just acquired recently Anglo-French because that's the way forward for a host of products in the years to come as well.

As with a lot of other pharma companies, we are also acquiring assets and focusing on a lot of -- number of platforms. So a lot of complex, really complex ones. I spoke about it a few minutes ago also about the fact that we are concentrating so much on complex injectables, on our inhalations portfolio. And let me add biosimilars. And the fact that OSD business is not going to be the focus area. And that's resonated with you as well.

From a global perspective, we believe that we need to be absolutely focused on efficiency. There are number of initiatives that we are taking to make ourselves a lot more efficient because there has been tremendous inefficiencies that have crept into the system over the last few years. But we are conscious of that, and we're taking all steps to kind of work on that.

We are also building operating leverage in our CapEx spend, as well as on R&D. Of course, the overall focus would be to really focus on product development cycles for development and to kind of compress that so that we are delivering top-notch launches from time to time. So, it actually helps in leveraging our top line, a continuous improvement culture, sentient culture, if you may. And of course, the global quality class. All of these, of course, are initiatives that we've taken and we're really going to focus on.

You would like to add to that, Vinita, if you may?

**Vinita Gupta:** No, I think it's fair to say, compared to what you saw us do in the past. We have simplified our strategic focus quite a bit. I mean, we used to have specialty in here. As you've seen in the last year, we've pretty much taken the specialty burn off in the organization.

Likewise, we have efforts underway to take areas like chemical entity where, again, we have established tremendous capability, but it does not really give us operating leverage in our current business, does not get valued in our current business, so finding the right path for those platforms are all efforts that are underway to really focus on these 3 core pillars of growth for the organization, which is doubling down in India, delivering on our complex generics platform and globalizing our complex generics platform.

When you look at our platforms like inhalation products, like biosimilars, like complex injectables, unlike the oral solid dosage business, these are global platforms. With the investment that we're making both in the pipeline and as well as with building capacities, it may cost us possibly ourselves so that we can, from an economic standpoint, get the end-to-end benefit.

**Ramesh Swaminathan:** Thank you, Vinita.

So, this is about the industry trends. You've also noticed that price erosion seems to have become endemic and so far as the American business is concerned. And we spoke about it just about a few minutes ago. In January, in particular, for example, we saw a 7% decline, whilst it accelerated to 16%. You can't obviously take one brush and kind of paint everything across the entire landscape. But the fact is there is -- it's really going to be product specific, portfolio specific, but it is there to stay.

The second thing that seems to be confronting everybody is secular inflation, inflationary trends across all sectors, across the pharmaceutical sector as well. This obviously puts pressure on our overall margins. And thus, obviously have been perhaps, again, there is tremendous need for looking at low intensity competitive launches. And many times I just spoke about the fact that we're going to focus on, in fact, inhalations portfolio, the complex injectables, the biosimilars and possibly even on the OSDs, niche launches, not actually capture what do you think is going to be value for customers as well as for our investors.

India business will remain strong. It's always been our focus for several years, and you have seen us grow in strength from time to time. It will certainly be extremely important for us

going forward as well. So, it will be -- it will encompass both organic as well as inorganic strokes. And the good thing about getting out of Covid is the fact that the FDA would begin worldwide inspections. And with that, it could be a double-edge sword. It could work in our favor because we have a pretty decent pipeline stuck without approvals. But it could also turn to be a double-edge sword and that it could also intensify competition, so to speak.

This is where Lupin is today from a market cap perspective. Next slide, please. It's about $4 billion market cap and revenue base is about $2.2 billion, EBITDA about $311 million. People are very familiar with this. Globally, we are the 10th largest generic company. We were higher up the league tables a few years ago, and we are sure we will get back there. The sixth largest Indian pharma company, the third largest in American from a prescription's perspective. And we are present in several geographies from U.S.A., Mexico, Brazil, India, and we are present in Australia, Philippines, South Africa and a host of other places. Our overall manufacturing footprint is about -- we've got about 15 sites spread across India. And of course, we have plants in America, in Brazil and Mexico. And we have 7 R&D sites, again, across various parts of the globe.

Next slide, please. This is a snapshot of what we actually -- how we -- Q4 actually was for us. As you can see, if you look at our performance over the last four quarters, it generally has been ranging between INR3,800 crores and INR4,000 odd crores. Q4, there was actually a decline versus Q3. This was led by, in fact, a slight reduction in India and of course, reduction in America. The reasons for decline in India is because Q4, in a general sense, is always the weakest quarter for India market.

You know that traditionally, Q1 and Q2 are very strong for India. Q3 and Q4 are a little tepid in comparison. This time around America, so we -- a number of people raised this question to me in the morning, why have we reached less than $200 million because that's what you had guided for at the beginning of this year in America. But the fact is there has been price decline. This quarter, we were also stuck with, in fact, some one- times. So, in terms of losartan, we had our recall – we're not able to sell and that actually -- the turnover and also the fact that there were returns associated with, in fact, the recall itself.

So together -- and there was a price decline across a number of products because Brovana, we ran out of exclusivity status also. Levothyroxine and others, there were some -- there was a price reduction. So to that extent, you would also appreciate that the acute therapy range that we have in our portfolio, unfortunately, in the last two years to three years, we have not been able to make a whole lot because acute therapy has not been selling in America or in fact, in most parts of the globe.

Then, of course, we talk about other therapy areas, including other SBUs, including API, who still have an issue in terms of acute therapy products, cephalosporins products. So, all of this has taken a toll and to that extent, Q4 has remained a little suppressed, so to speak. And if you look at the EBITDA margin, it has also come down. There's close to INR127 crores impact only because of the fact that our sales were lower. But apart from that, there was, of course, the impact of several one-times. This is including the losartan recall and the costs associated

with that. As you might also know, we lost our litigation for Solosec in terms of royalties we paid to the vendor and there were associated litigation costs and the like. So, all this actually took a toll. So, the one-time that actually comes into overall expenditure base.

Apart from that, there was a swing from the last quarter because last quarter, there were settlement incomes, and those did not figure in this quarter. So actually, the swing is a little more marked in terms of -- it's been a -- this big swing vis-à-vis in the previous quarter. The last was 13.7% on a normalized basis. This time, it came down because the sale as well as the one-times that we took, plus, of course. There were other developments, which are very noteworthy and important.

We acquired Anglo-French. It was actually consummated in the first week of April, but important development, obviously. We also expanded -- we had a bolt-on acquisition in Australia, a very important one for us. We announced partnerships, strategic partnerships in China and then, of course, supply arrangements in China again and for other important products for Peg G-CSF and so on. You see the FDA approval for a number of products, 3 products as such. And of course, we had our inspection of our Tarapur facility last quarter.

Next slide, please. Vinita, this is really your -- would you like to speak about America?

**Vinita Gupta:** Sure. Sure. So, I think most of this is known. But if you look at our position in the U.S., certainly, we have a very strong market position with 44 products. We are market leaders. A very heartening development with albuterol. All of you know that we entered a little bit later than our competitors/ our peers in albuterol, but have now got 22.6%, almost 23% market share, so have ramped up very nicely.

And when I look at Albuterol, Brovana, now inhalation products are over 25% of the company's -- the U.S. business revenue, a bigger part of the U.S. profitability. So, the transition into complex generics, certainly, in relation, it's happening. We need to accelerate it, which we are looking forward to in fiscal year '23 as well as '24. We have material launches into the US. We have a good number of our portfolio. We are in 60 products in the market, 113 products. We are in top three in terms of market share. And a good number of products that are pending. So, from a pipeline perspective, when we compare it with all of our peers, we have one of the richest pipelines, both in terms of number of ANDAs that are pending as well as the complex products that we have above -- within the pipeline that gives us the headroom like Ramesh was saying, based on the conversation with some of you that our market cap pretty much reflects only the India business.

We have tremendous upside here with the pipeline that we have built on the complex generics front for the US. On the revenue front, as Ramesh mentioned, we had softness in Q4, in particular, due to a couple of products, Albuterol, primarily phasing. We see Albuterol -- really again, the winter month is the volume is higher and then tapers down. So, we saw some of that, plus we had a regional competition in Brovana. So, we saw the impact of that. And we had the recall of losartan. Those were the three material reasons why revenues were down in

Q4. And we launched a couple of products. We launched two products, small, though in the scheme of things.

Our material products, we expect to really now in the next 12 months, the launch of Suprep into the U.S. And then later on in the fiscal year, we plan to launch Spiriva as well as FDA permitting Pegfilgrastim. So, we've had challenges this past year. I'd say it's been a year of really making the U.S. business stronger from a processes standpoint, from a balance sheet standpoint. We had a number of one-time impacts of gross to net items like FTS works that we cleaned up as well as returns, inventories for the flu season products like Oseltamivir and cephalosporin. So, we believe that we are in a strong position, but still need new product launches to grow the business.

I mean, all of you have been close to the marketplace and the trends in the U.S. Our pricing pressure is still strong, especially on the oral solids. We continue to see double- digit pricing pressure. And so the only way to be able to grow both on revenues as well as profitability is a combination of new product launches and material new product launches, as well as continued cost reduction and optimization and both are a very strong focus for us.

**Ramesh Swaminathan:** Thank you, Vinita.

Next slide, please. Nilesh, would you like to take on this India business?

**Nilesh Gupta:** Sure, Ramesh. Yes.

So we feel that -- we feel very good about our India business. I think it's just coming into its own, and I think there's a lot of room for us to grow in India. And we're really exploring all kinds of things in India. And we'll talk about some of that. So, as we fixed the U.S. business, I think the core India business, we definitely want to double down on. The Q4 growth was tepid. We grew at 5%. And then I think that's an industry trend at this point of time, especially the Covid drugs as they come off and the additional market that happened on the Covid counters had come down. You will see sluggishness for the market.

You'll see sluggishness for -- you'll see even market decline. I think in April; the market is actually declining for the industry. We were not positively impacted by the Covid products; we really didn't have any. And therefore, we'll not be negatively impacted materially as well. So, it should be good growth. It should be a good growth year as long as Covid doesn't play spoilsport anymore. Hopefully, it's behind us. But the India quarterly sales, as you can see, goes as norm Q4 is always weak. You see a high Q1 coming up, thereafter. Year-on-year, yes, last Q1 was big. So from that perspective, you won't see that growth, but you'll see that growth in coming quarters as well.

Our focus is chronic amongst a peer set where the largest -- our proportion of sales from chronic therapy areas is the largest and that continues. And our big three areas are cardiac, diabetes and respiratory. As you can see from the slide, we're growing faster than the market in all three. We are not satisfied with this growth rate. We think we can do better. And

certainly, FY '23, but the period days beyond as well. You should look at stronger growth coming from Lupin in these therapy areas, but overall for our India business as well.

Three brands in the top 100, 8 in the top 300, that statistic has been improving. Again, not satisfied with it. I think there is, again, more room to grow there. Double-digit growth in areas like respiratory and gynecology and we're launching new divisions as well. So, we launched three divisions, one for diabetes, one for CNS and one for anti-infectives. Like I said, I think it's an extremely fragmented market. There's a lot of room to grow. It's our home market. The U.S. and India are our 2 home markets. So, we have to do well in both those markets. And certainly, there's a lot of room to grow in India.

Ramesh, back to you.

**Ramesh Swaminathan:** Yes. Thank you.

These are the other markets that we are present in. So, essentially, we've made some good progress across various markets. On the EU5, for example, we also -- Fostair was introduced, and we have been ramping up on NaMuscla as well. Australia, we made this acquisition, Southern Cross, which we believe would serve us good in the years to come. South Africa, now the fourth largest generics player, and of course, been a market leader in cardiovascular space for quite some time. Brazil -- so that's been a loss-making unit until very recently, but it's turning around pretty nicely for us. Mexico, we are market leader in ophthalmology, number two actually, Sophia is number one. But in terms of values and then in developing a national footprint, we really are going the full hog out there.

And of course, API business -- our fortunes have dipped this year essentially because of acute therapy products not selling in most parts. But I understand the JV business continues to do pretty well. Some headwinds in India on the TB front, but overall, still good growth. And as you might know, we are looking at getting kind of broad-basing our overall portfolio of products that we serve for the global institutional business.

Next slide, please. The P&L, essentially, this is a snapshot. This was actually provided previously. We spoke about the fact that there has been a slight decline in overall sales. And we also spoke about the reason why there was a decline in overall EBITDA margins. And there are, of course, exceptional items from a write-off perspective also. This time around, we had accelerated amortization of certain intangibles in Gavis, which we took this year. And overall, given the fact that we actually had a huge exceptional items in Q3. We had -- we ended up with the entire year at an overall loss situation. But just to add, that the next two quarters could potentially be -- might have the same lackluster feeling. But the second half of next year onwards, you would actually see a step up in terms of sales, as well as in terms of the margins that go with it.

As Vinita was saying, there are a number of products that we are looking at for America over the next several years. And for sure, I think this would begin in Q3 with Suprep and that's something which we already have an approval for. This is again a snapshot of what we spoke

about. Essentially, the annualization of our annual results for the year, for the company. And I guess it's something that we just spoke about in terms of the exceptional items, making this a very exceptional year in some ways.

Next slide, please. Yes. R&D, as you can see, it's been running steady at around INR350 crores, INR375 crores mark, so to speak, and now it's around the 8% mark. But more importantly, the character of R&D is shifting. As Vinita was also saying, it is going to be more -- a lot more focus on complex generics, so it's going to be inhalations and the injectables and biologics all the way -- biosimilars all the way. And of course, the salience of NCE would certainly come down over time.

There's been a tight rein on overall capital expenditure. As you can see, we used to -- it used to be in the INR1,800 crores range. It's hovering around the INR600 crores mark, but there's a lot of impetuses on reining in the CapEx cost expenditure outlays. And of course, from being a cash surplus company, there is a slight increase in overall debts. There's tremendous scope for potentially working on working capital optimization. It's around 145 days currently, and we and my team are working on optimizing on that. It turned out to be a debt situationally because the fact that we had to pay up the settlements related to Glumetza, but that is one-time. It's a question of time if we kind of get back into the surplus situation until we actually start using it for productive purposes, including M&A. And that's something that we are saying, you'll be looking at in India and worthwhile acquisitions in other parts also.

Next slide, please. Really, your slide, Vinita. If you want to talk about complex generics, you're passionate about it.

**Vinita Gupta:** Sure. So, as I mentioned that the focus on the pipeline front to grow the business is certainly on the complex generics. And we have pivoted from an R&D standpoint from oral solids into complex generics. That's not to say that we don't leverage our oral solid platform. We have tremendous capabilities and capacities from a plant perspective, established there as well. So, definitely chasing material opportunities there, but really going -- making sure that all of the material pipeline opportunities on the complex front, whether it's injectables, inhalation, ophthalmic, derm, we cover them. And right now, I mean, pipeline is rich with all of the material products across these platforms.

Next slide, please. So this is really what our pipeline looks like. It covers $70 billion with our products going off patent. And as you can see, the oral solids are now 15% of our pipeline, biosimilars 30%, just given the sheer scale of the biosimilar products by market size; inhalation, 25% of our pipeline and injectables, 22%. Also a small percentage of women's health and depot injectables. We have captured separately from injectables. So, roughly injectables is 30%. So, when you start looking at inhalation, injectables and biosimilars, roughly 30, 30, 30, material opportunities across these three platforms.

**Ramesh Swaminathan:** Yes. Next slide, please?

**Vinita Gupta:** So -- again, this is continuing on the same theme. We have already started monetizing our inhalation platform with products like albuterol that we have monetized in the US. Now a solid product for us. And some of these platforms, as you can see from the flags that we put in there are geographic. We have the potential of leveraging across multiple geographies. So, on the inhalation front, we also launched Fostair recently as said in U.K. and have plans to launch other inhalation products in U.K. and Europe as well, as well as China.

So, the inhalation platform has started and in the next couple of years will really become a material part of our business, as well as geographical spread. I mean right now, we have albuterol, but looking at the next 12 months, Spiriva and then Dulera and Fostair. We have Qvar, the next wave of DPIs, MDIs, the Ellipta products, the Respimat products, all in the development on the inhalation front.

On the biosimilars front, again, multiple geographies that we are addressing. And the focus has shifted from, of course, our first program, pegfilgrastim, for the US, which we're looking forward to bringing to market soon, the products where we can be in the first phase, where we are in first or second to launch and have the potential of really getting major upside as well as a strong long-term position.

On the injectables front, after inhalation and biosimilars in fiscal year '24, we will see material launches coming through. We've had a number of complex filings. This past year, we have had our first peptide filing on the products like ganirelix, products like glucagon, our Risperdal Consta on the depot front, that's pretty far along. We hope to be the first company to file a 505(j) for Risperdal Consta and so on and so forth. So, material pipeline, complex product pipeline on the injectables front.

On the women's health front, we've made significant progress on the drug device combinations. Products like Nexplanon and Mirena, we've already got proof-of-concept and have put these products into the clinic. Again, from a timing perspective, it's inhalation now, biosimilars next, injectables soon thereafter and women's health in the 4-year to five-year time frame.

Next slide, please.

**Ramesh Swaminathan:** It's basically what you've already spoken about.

**Vinita Gupta:** Well, I think I've probably spoken to most of this. I mean, on the inhalation front, we are pretty much chasing all of the material opportunities. Products where we are late, we don't intend to get in because there's enough opportunity to chase. And really, in terms of sizable market opportunities apart from the US, Europe turns out to be a material opportunity for us on the inhalation front followed by North America, Canada, Australia, Japan through partnerships and even China.

Next slide, please.

**Ramesh Swaminathan:** I think one -- just a flavor here, a colour. Essentially, we have two DPIs and four MDIs under development. And we, of course, have 2 products in the market and we have Ditropan coming end of this year first phase.

**Vinita Gupta:** Yes. This is on the injectable front. We talked about this as well. I mean we have -- yes; we can move on to the next slide.

**Ramesh Swaminathan:** Injectables. Next slide, please. Biosimilars.

**Vinita Gupta:** Yes. So on the biosimilars front, of course, we started with Enbrel that we launched in Japan and then Europe through a partnership with Mylan. That continues to evolve. Mylan continues to launch in multiple countries, and we expect our share to build over the next 12 months to 24 months with Etanercept. The U.S. is still long away, still 2029. But needless to say, we have reserved rights of the product for the U.S. market.

Pegfilgrastim, while we are a late entrant on Pegfilgrastim, really, for us, we will start learning the market through it. And hope that in the next 12 months, we get inspected by the FDA and we'll plan to launch the product. We're very pleased with our position actually on the on-body Onpro product, where we seem to be one of three and potentially in the first wave. Our customers are very, very keen to see us in the market with that product. So, we think we will really grow pegfilgrastim materially with the launch of Onpro, which is 10 months behind the pre-filled syringe but it's going to be a material anchor for us on the biologics front.

Lucentis is well under -- when we had some delays in the clinical trial with Covid, but now it's well underway. And again, very strong partnership position in the U.S. that we've already established for Lucentis. We'll share more as we come closer to the opportunity. And right after that is Eylea. So, on the ophthalmic front, both Lucentis and Eylea are going to be material opportunities for us that we would leverage through the channels that we have established relationships with. And then we have programs earlier stage in the pipeline that we are pursuing.

**Ramesh Swaminathan:** Next slide, please.

**Vinita Gupta:** Go ahead.

**Ramesh Swaminathan:** Yes. I will go ahead with this. So as I was telling people, there is a lot of things that we would pursue and there are lot of inefficiencies that have crept up in the system over the last few years. So, we are working on all of this. There is, of course, considerable idle time because we programmed for a lot more capacity utilization and went ahead with a lot of capacity expansion at various -- in the factories, both the API and formulation. So, there is considerable idle time out there, which we want to clear.

It obviously would be coming down on expenses, perhaps footprint, addressing the manning background in various parts and the like. So, we are doing a lot of stuff on that front. We also

know that there is a lot of write-offs in the system because we've been dropping products. Demand has been coming down and the like. So, there's a lot of scope for reduction of retarders, value eroders, if you may. And we're working on this as well. Given our supply chain issues and OAI status and so on, we also had issues on airfreighting.

So, ideally, if you go back about five years ago, 100% of our products would have been ocean freighted, so to speak. But over the last few years, there has been a considerable element of air freighting, which has been happening. We would like to pull down on that -- claw back on that and go down to ocean freighting and that would mean considerable savings on that score.

There are, of course, returns associated with the -- there are various kinds of costs. The returns were essentially because of product recalls and the like and normal returns. I think there is scope for optimization on that in India, as well as in America. We're working on that. This might seem like an anomaly. Whilst we have idle time, we have also a failure to supply, which has actually, again, eroded our bottom line tremendously over the last couple of years. We believe that if you were to pull up -- go back on all of this, save on all of this, optimize on all of this, including pulling back on low-margin SKUs, there is considerable scope for improvement in our overall performance.

I think the figure rest anywhere between INR500 crores to INR1,000 crores. So, it really depends on how much we can pull back on and how fast can we do that. So that's one of the things that we are taking on as a company, and you'd like to expedite this, not -- actually to deliver good results for ourselves, live up to our potential and deliver for our shareholders. This would obviously mean optimizing on the network, optimizing on the R&D front and looking at the entire business at an integrated fashion, and we've got the right technology tools to kind of work on this as well.

R&D optimization, would you like to speak on this, Vinita / Nilesh?

**Nilesh Gupta:** Next slide, please.

**Ramesh Swaminathan:** No, no. Yes. Okay, R&D.

**Nilesh Gupta:** I think we talked about most of this already. So, we've optimized the R&D spend, but I think we're chasing the right opportunities. Clearly, the size of the prize on the oral solids has come down, and the optimization is largely in line with that. But our key initiatives on the inhalation side, the injectable side, we are pursuing. Biosimilars, I think we're still cherry picking. The idea is to have products that come in the first wave. Etanercept was different. But -- and I think we learned a lot through. But if you sort of look at the rest of the pipeline, that is intended to be first to market or one of two or three players in all.

So, the optimization on the R&D, we feel good with this number. And I think we're going to be able to stick with this kind of number for the foreseeable future. Or we'll possibly bring it down a tad even. But I think we're seeing all the right opportunities that there are.

Obviously, I think we have a wealth of portfolios and platforms to work with. But the filings that we have are huge as well. So 457 filings to-date. There's still another 160 pending approval and a bunch of first to files as well. A lot of that in -- close to end of this fiscal and in FY '24 onwards, you'll start seeing those coming to market. I can't see the bottom. I think I've touched on most of that already.

So Ramesh? Yes. I think that's it, right?

**Ramesh Swaminathan:** We've got one more slide. So, Lupin has always been applauded for the quality of its manpower. We always come across as a very professionally-led firm. The quality of the professional's kind of speaks for itself. The first family included, they are professionals and hard professionals and behave in the way they come across also. And they rank pretty high in the world table, the league tables when it comes to being the most powerful CEO amongst women and the like.

A lot of awards to a host of other professionals at Lupin, right, from -- and of course, several functions, manufacturing, quality, professionals like a CIO and the like. So we've got a lot of those. And I would think that these would keep coming up because we're only going to do better from now. That's a result that we have taken, and we would live up to that expectation also.

Thank you. We'll move to discussions.

**Moderator:** Thank you. We'll now begin questions and answer session, However, wants to ask question may raise your hand, you can just introduce yourself with your company name and ask the question.

**Pritesh Vora:** This is Pritesh Vora from Mission Street India. I just want to understand what is our total investment made in the biosimilar pipeline until now? And what do you see the total when the revenue start coming in that particular stream? What will be the US-led revenue? And what will be the rest of the world led revenue?

**Ramesh Swaminathan:** I'll take on the first part of the question. So, when you speak about investments for biosimilars, the first biosimilars that we developed -- we actually developed in partnership with a company called Yoshindo. To the extent, a huge chunk of the costs was borne by our partner. So, we've actually been a little calibrated the way we went about that, what we thought was untested in some ways.

Even today, a lot of our biosimilars is essentially under partnered programs and not from a financial perspective, whereby the risk of development is actually borne by the financial partner, whilst we share in the success when it actually gets launched. And so we share in the spoils when it comes to commercial success really. So, to the extent, we have kept our overall risk -- the risk associated with that to the very minimum.

**Pritesh Vora:** Any particular figure? How much investment has gone up till now in that particular time?

**Ramesh Swaminathan:** So, the investments are two kinds. One is, of course, on the development of the pipeline. The other is in terms of investments for the infrastructure itself. And that's -- it's minimal right now. About INR2 crores, INR3 crores it comes overall together.

**Nilesh Gupta:** Yes. About $15 million to $20 million a year would be our total biosimilar spend. And then on top of that, there is funding for the key programs as well.

**Pritesh Vora:** There are couple of things, so even during the course of the year, we have taken some

**Nilesh Gupta:** No, per annum.

**Pritesh Vora:** Per annum. And how many years this investment has gone?

**Nilesh Gupta:** It's on the increase, so it wasn't at that run rate. But we've been investing for 10 years, but I think it started really small numbers. And I think this is kind of the steady state that we see right now.

**Pritesh Vora:** Right. And what is the economics there? How much -- when you made this decision to investment, did you see how the investment will be recouped from U.S. geography or rest of the world, if we can throw some light on that?

**Vinita Gupta:** So we -- like Ramesh mentioned, we've had a very calibrated approach on biosimilars, just given the uncertainty and the fact that we are still learning that market, and the market is still evolving. I mean like Etanercept, we had that R&D cost sharing with Yoshindo.
Likewise, on other programs, we have got financial investment and upside sharing. So, in a way, some of those programs, you're going to look at all of it as an upside, if the program is being funded by a partner. So, in terms of the revenue split right now, I mean, obviously, it's all Etanercept and it's small. And it's going to be all ex U.S. right now. In the next year, as we launch pegfilgrastim, we'll see a material shift to the US.

And as we have ranibizumab as well, I mean, if I look at ranibizumab, it's 50-50 between the U.S. and Europe in terms of market opportunity, but we have a bigger opportunity in the U.S., just given that the customer -- the channels are very similar to the folks that we have established relationships with; the ophthalmic, specialty channel, for example, through our wholesaler relationships is what we will be able to leverage for a product like ranibizumab or a product like Eylea. So, you'll see more of revenues in the U.S. and partnered revenues ex-US.

Yes. Hopefully, that answers your question. Yes.

**Ramesh Swaminathan:** There is a question in the back.

**Kunal Randeria:** Kunal Randeria from Edelweiss. So, the first question on the domestic business. This quarter, I think there was a 5% year-on-year growth. Last quarter, it was around 7%, right? And given that, you have such a strong chronic portfolio and no real Covid impact in the base. Any particular reason, anything to share where you're missing, what investments need to be made?

**Ramesh Swaminathan:** Sure. So first of all, that's India business. So that includes the tender business that we do in India as well. So the India prescription business was 13.9% growth year-on-year. So that's why I don't see a concern with that business growth rate as such. So, if you take out -- the tender business was lumpy. We're getting back into some of those tenders going forward as well. You'll see it normalizing, but we do report the India prescription business along with the other business, formulation business that we do in India. But otherwise, it was 13.9%.

**Kunal Randeria:** Okay. Sure. And secondly, the price erosion numbers in the U.S. that you share, they seem a bit scary. And obviously, this is not, I mean, good for the industry and for the health of the industry. So, I'm just wondering when do you see companies starting to withdraw from molecules? How far do you think we are? Because I think you saw something similar in 2019 when a lot of these US-based companies started to do it. Do you think it should start now?

**Vinita Gupta:** You're going to see it. I mean, all of the generic companies, all of the generic major CEOs that I've spoken with in the U.S. are complaining of the pressure on the industry. And we have also conveyed to our customers the three big buyers that we're going to have to exit. And they are concerned because for some of them, we are the largest suppliers. But we have told them that we don't want to be your largest volume supplier. We also want to be a large value supplier.

So, I mean you're going to start seeing exits. We, actually, for the first time in the company, put together an SOP for a very planned exit so that we can -- when we look at taking a product off that does not -- that has negative margin, we're also addressing the plant cost, the idle cost that is associated with it. And what's happened is on the oral solid front, I mean there is too much capacity. And people are willing to really to be able to make some money on that overhead. They're willing to sell product at 5%, 10% margin, which doesn't make sense. So, you are going to see exits. I think you're going to see exits from us. And we already have had a few, and that's why you see that impairment on Gavis. There are certain products that we just decided to discontinue manufacturing. Likewise, you're going to see more.

**Prakash Agarwal:** This is Prakash from Axis. My first question is on other expenses. So, last quarter, 3Q, you had called out a couple of items. And this quarter, in the commentary, there is a mention of freight and input costs, obviously, would be in materials. But what has really changed? I mean, we would have expected the other expenses to come down QoQ?

**Ramesh Swaminathan:** Yes. So there are a couple of parts to this. And so if you look at -- so there's, of course, losartan and associated recall costs and also stocks associated with that, etc, paying it off. You talk about manufacturing other expenses, right?

**Prakash Agarwal:** No, other expenses, which used to be INR700 crores, INR800 crores, now it's INR970 crores.

**Ramesh Swaminathan:** Yes. So, that is essentially -- one part of this, essentially, there's a slight decline in our salary costs. Some of this actually got accommodated because the incentives that we give to the sales force and the like, the shift to expenses of a different kind, and that is what is actually being brought out there.

**Prakash Agarwal:** So, what I'm trying to understand, like all the other expenses, which is either the marketing-related, traveling, freight, etc, is there any one-off apart from losartan recall or it is the new normal.

**Ramesh Swaminathan:** As I said, there's a shift in between heads there, and that's what actually.

**Prakash Agarwal:** That would be marginal, right?

**Ramesh Swaminathan:** No, it's significant. It is significant for the manpower first line to that line.

**Prakash Agarwal:** Okay. And losartan would be significant?

**Ramesh Swaminathan:** Yes. So we also had Solosec litigation costs and the associated penalties that we had to pay. So, all of this put together.

**Prakash Agarwal:** So, normalized levels would be what, sir?

**Ramesh Swaminathan:** So, you would say that the overall. So the losartan and other costs, et cetera, would have cost us about $11 million over there, $10 million to $11 million. And there's about, I would say, about $6 million in terms of -- $5 million in terms of shift from one expense to another head.

**Prakash Agarwal:** Okay. That's fair. And second for Nilesh, on the US...

**Ramesh Swaminathan:** There is also a swing as you might -- if we just were to compare Q3 and Q4, we also had settlement income. So essentially -- this is not there. Yes. Q3.

**Prakash Agarwal:** The NaMuscla one or which one?

**Vinita Gupta:** This is other expenses.

**Ramesh Swaminathan:** Other litigation settlements. Yes.

**Prakash Agarwal:** Okay. On the U.S.

FDA side, I mean, we were very hopeful like with Goa happening, Somerset and all would start getting remediated. What is really -- I mean not playing out is FDA -- what is the commentary by FDA now? As we hear, like you also put in the -- your commentary industry trend, it is all over the place, 4, 5 teams are in the country. So, what's really playing out?
Are they stricter now? Or -- and we had all the time in the world, two years to pull our socks. So what's really not playing out for us and for the industry?

**Nilesh Gupta:** Yes. So, I can speak. Let's start with the industry first. So, I think the big industry part is, there was definitely a hiatus of inspections in the last two years. And obviously, the FDA is now ramping up inspections within the country. And we're going to get mixed outcomes basis, basis that -- basis of the readiness of the individual company.

I would say for Lupin, just because of the geographical location, I would say that the India plants are operating under one leadership structure and one set of principles. The overall SOPs and are all the same, but I think local implementation, there might be some nuances, which will be there. We had some leadership gaps in Somerset, both in manufacturing and quality. And I think both of those led and both of those positions have been replaced and filled back.

We are not happy with what came out of Somerset, but I think Tarapur is representative. So, I think, obviously, we had certain observations. We were able to address them to satisfaction with the FDA. And we would certainly hope that Tarapur goes the same way. We've sent in our response, end of this month. Next week, we'll send in an update as well, basis which we should see the outcome of that inspection. And then that's what I would expect for the other inspections as well.

We're very clear that we have to get across this compliance rut that we've had. It's been going on for 5 years. And I think what we have set up is pretty solid at the OpEx level from a governance perspective, bringing in people like Diana in the US. I think that is a great opportunity for our people to learn to be -- to become best-in-class as well. So we're committed.

I think we -- it's there in the comment. It's an aspiration. We're certainly not best-in-class at this point in time, but we know that we need to be best-in-class to be a strong generic company. And for the India plants, I think we're there. We have inspections, obviously, which will come up for Pithampur unit 2, and for Mandideep. These should go the same way as well. And Somerset, I think there's a very clear plan on remediation as well. Again, we had a set of observations. We had a set of observations.

Again, our track record does not speak well for Somerset. But the team is extremely motivated to fix it, and this is kind of their opportunity now. They need to fix this now. And we've given them the tools. We have the people, certainly whatever resources that they need as well. We should come out of these now.

**Prakash Agarwal:** So how many approvals are pending for the key facilities like, which are really stuck now? So for example, you speak about 160 pending. So Somerset, your Pithampur 2, couple of more which are under U.S. FDA scanner, how much are actually locked with respect to new approvals coming?

**Nilesh Gupta:** So Mandideep, there's nothing. Obviously, cephalosporins is launched and everything. So we have one cumulative, there, obviously to fix it. There's nothing. In Tarapur, there's one or two products that are stuck basis that Tarapur status. At least one of which we are site transferring as well. So again, there's very minimal exposure coming out of that. Less than 5% of our revenues come from FDA impacted sites, first of all, of our U.S. generic revenue.

Pithampur 2 and Goa were the two big sites where there were a bunch of products stuck in Goa. You've seen some of these approvals coming. We'll do at least seven launches out of Goa this year, and there's another 15, 20 that will come over time as well.

Pithampur is even more. I think there's about 30-odd products, which are stuck with these FDA compliance. Some of them won't launch anymore because the time value of those opportunities is gone. But there's still some extended release products that I like. I think those are all really good opportunities to launch. So that will come out of Pithampur as well.

None of these are big swingers. I think the big swingers come out from inhalation, from injectables, from biosimilars as well, some first-to-files as well. Those first-to-files are from -- some of them were from Pithampur. We transferred some of them. They're mostly from Nagpur and Goa, and those are protected.

**Prakash Agarwal:** Somerset, you said is how many pending?

**Vinita Gupta:** So, Somerset, the biggest one right now is Suprep that is next quarter. And then other products, we have tech transferred. So all the first-to-files. Roughly 20%.

**Ramesh Swaminathan:** Zero odd products pending out of Somerset.

**Prakash Agarwal:** Suprep would be from there, which would -- which has approval.

**Vinita Gupta:** It's the final approval.

**Prakash Agarwal:** It should not have an impact.

**Vinita Gupta:** Right. It's that final approval. So we're doing validation batches now.

**Prakash Agarwal:** Understood. And lastly, GAVIS, how much is actually sitting in the balance sheet now?

**Vinita Gupta:** $100 million?

**Ramesh Swaminathan:** About $110 million. Yes.

**Prakash Agarwal:** So of the $900 million, about $800 million has been...

**Ramesh Swaminathan:** Amortized over time, for sure.

**Vinita Gupta:** Yes.

**Saion Mukherjee:** This is Saion here from Nomura. So first question is on India. I mean, you talked about acquisition and 10% to 12% growth that you're talking, you are factoring in acquisition. There are some headwinds that I see like some of the licensed products like Cidmus is not there with you, and then linagliptin goes off patent. So how are you thinking about that? I mean how important would be M&A? And just if you can comment on Cidmus because it's a brand, which you had built and you couldn't retain it. So why not like spend INR450 crores, INR500 crores, whatever it takes to sort of run with it, right? I mean, there seems to be a mismatch with your commitment to India and not being able to retain Cidmus?

**Nilesh Gupta:** No. So first, I will clarify on that. But I think the -- I think the 10%, 12%, first of all, is organic. It won't happen this year because we have Cidmus going out. We have certain exclusivities, which are running out as well. So our growth this year will be sub-10%. But if you normalize it for the in-licensed product, you will actually see much higher growth. And I think the ongoing commitment is to grow at that 10%, 12%, sometimes stretching it to 15-odd percent as well. We're very keen on acquisitions in India.

Cidmus was something that we revised offers for multiple times. We built that brand. Obviously, from our perspective, we were very clear that we want to own that brand at the end of it as well. I think the valuation stretched it to a limit where we were not comfortable, and we finally decided to let it go. I don't think the intent is -- I don't think you should read that as a commitment on what is there and not even a commitment from the inorganic side. We're keen to acquire in India.

There's several assets that we're chasing at any point of time. But you've seen the story in India, right, the valuations do some -- go out of control. Once it goes out of the seven- year, eight-year payback period, we are not necessarily comfortable. So if it goes beyond that, usually, that's when we would walk away. I think we were at five, six. We went to six, seven. Now it's seven, eight. I don't think we'll feel comfortable at 9 years, 10 years at this point of time.

That's where Cidmus would have gone with where it finally ended.

**Saion Mukherjee:** And second, on execution, I mean you've been facing a lot of challenges globally. I mean, particularly in the US. Just wondered to understand from you, what are the (technical difficulty) you talked about Somerset leadership gaps and that sort of -- was one of the reasons where there was a shortcoming. Are you facing any issues on the leadership front or in the manpower front because with all the issues that the company is facing? And how are you trying to internally sort of address these issues because one would expect exits and one would expect a lot of churn. I mean, what's happening if you can just throw some light on the softer aspects as to how you ensure that you execute on whatever you're thinking.

**Vinita Gupta:** So, there has been a lot of churn actually on the management and leadership level. When I think about both in U.S. as well as India, we face a challenge. Market has been tough. And one -- so we wanted to change ourselves like in Somerset, Nilesh mentioned, the Head of Operations was a position that we changed and brought in someone very solid from Teva to lead the site at the manufacturing level. And on the quality front as well, we felt -- there we had a turnover and then we brought in a person from the outside. And continuity becomes a problem when you have that kind of churn.

So, we have faced it. At the same time, we've always tried to scale up when we've had turnover. And now when I look at some of our G&A functions in the US, I mean, when you look at finance, for example, HR, IT, all of them have turned over. But we have, again, scaled up. We brought in capabilities that have helped us clean up a lot of our baggage from the past. For example, the FTS cleanup that you have seen in the year, unfortunately, it hits the P&L now, but as a cleanup that should have happened over the last couple of years. Likewise, the

processes that the team are now very, very strong going forward for the organization. So in the last year, we've also focused a lot on really putting in contemporary processes.

We found that some of our basic processes for supply chain, which is crucial for a generic business were challenged. They were antiquated, to be honest. They were set 10 years ago, 15 years ago, and we had a need to really revisit them so that we can really be better in terms of predicting what our next six months, next 12 months, next 24 months looks like and take proactive decisions to get out of product or to manage the failure to supply penalties in a strategic manner. And we have done that. We implemented IBP in the company this past year for the U.S.

Right now, we are doing it ex U.S. for all of the developed markets and then the rest of the company. So, we are -- we have taken the time in the last 12 months to really set in very, very strong processes. So, of course, at the end of the day, leadership and people drive the success, but processes are equally important for a company to scale up.

**Nilesh Gupta:** Vinita, if I can add -- so I think the one big area that we are fixing and focused on is the U.S. generic business. So, first of all, people within Lupin, obviously, and people within the industries, but I think they get it. I think they see that -- that's the one big area that needs to be fixed. I couldn't help, but smile when you asked that question because I think we're obviously able to attract all the talent that we would want. And attrition has always been a part of this industry. It's always going to be a part going forward as well.

Obviously, people like to be part of a winning team. People see that there is this period where there is -- where there are challenges that we need to work through. So obviously, we talked about optimization on R&D, on manufacturing and the like. But we also talked about a very clear pipeline that we will deliver on. I think the complex generics pipeline that Lupin delivers, obviously, that's completely getting discounted at this point of time. And I think we have to reflect that into results. But people who work closer they see it, right? So they see products coming into the pipeline. They see products going into the clinic, approvals, launches. We have an extremely motivated team. And we obviously -- I think that's -- Vinita and my, one of our prime responsibilities is to make sure that, that team is engaged to deliver on the goals that we have.

**Saion Mukherjee:** Just one last point. Sir, on the cost front. So basically, the issue is that the margins have been all over the place, right? I mean, whatever numbers we had, and I can understand the issues there. So, if you can like handle and give some more granular details, like you've talked about INR500 crores to INR1,000 crores in terms of pipeline. And you had mentioned five or six areas like idle time and failure to supply. If you can quantify those, so that we can sort of have a greater handle as to what to look forward to, because it's very unclear as to from a single-digit margins, we'll travel up to 20%, right? So, there's no anchor out there. So, if you can really help us and guide us like to how should we build our model as we look forward?

**Ramesh Swaminathan:** So, well, the INR1,000 crores is obviously we achieved over time, and that's what the endeavor is all about. So, we have begun this process and so far as the plants are concerned. We're doing what it takes to kind of reduce the idle time out there. First, of course, the footprint and the manpower redressal, all of this is part of that. Maybe what it takes to bring down

inventories, monitoring it more closely. The FTS is more under control right now. We are trying to move out of -- it's an iterative process, moving out of, in fact, low-margin products and the like.

And there are issues like airfreighting. So that's focusing on -- especially if there's capacity expansion required for that particular product, we would go down that drought or look at how else can we actually build up inventory. So, we come out of that as well. There a lot of fires -- lot of irons in the fire. I can't go down the path of -- actually quantifying initiatives. All of those put together would come to that. There's, of course, some inefficiency when it comes to, for example, our make us as buy decisions on API itself. We are addressing that as well.

So, all of that will get this done when it comes to recruitment that we're speaking about. In terms of the results, we believe a huge chunk of it will potentially land up during the course of the next fiscal. So it could be upward of INR450 crores, INR500 crores, so to speak, and potentially the balance over the next one year.

So even if you were to with the -- coupled with, in fact, the top line leveraging that we're speaking about, the products coming in and the like, the exit run rate should be pretty -- exit run rate for next fiscal that is. This fiscal, sorry, FY '23, should be kind of reflective of what we can look forward to in the years to come. And this will be more representative of what we have achieved in the past as well.

**Vinita Gupta:** Let me just add. I mean, from Q2, you should start seeing the impact of a number of the INR500 crores level of initiatives around the areas that Ramesh spoke about starting to kick in, along with product launches like Suprep and then others in the second half and then the full impact of the cost reduction also into next year. And on top of that, like I was mentioning, we are working on externalizing areas like the NCE, which again is a $20 million burn on the company. Last year, we had mentioned that we are working on 3 areas: specialty, NCE and biosimilars. So, specialty is all done.

We have completely gotten rid of the burn of specialty. NCE is -- we're working hard to get rid of that burn right now and believe that second half of the year, we should be able to get those savings. And biosimilars also we are working on a product level risk mitigation or portfolio level risk mitigation to reduce that burn to be able to improve our margins. So all of those will kind of different points of time in the year, but the INR500 crore plan we have put it into our operating plan for the year starting Q2 and then more leverage to come through externalizing some of these burn items that don't give us the upside from a business perspective.

**Moderator:** Now we will take online questions. The question is from Hitesh Sharma. Next question is from Krishnendu Saha.

**Krishnendu Saha:** Yes. Hi. Can you hear me?

**Ramesh Swaminathan:** Yes

**Nilesh Gupta:** Yes

**Krishnendu Saha:** Yes. Just a question on the US. Can I ask whether U.S. is profitable as of now?

**Nilesh Gupta:** Sorry, we lost your…

**Moderator:** Can you please repeat your question?

**Krishnendu Saha:** Yes. Just a question on the US. Can I ask whether U.S. is profitable as of now?

**Vinita Gupta:** Adjusted for the one-time just because we had a lot of one-times, it is profitable at the EBITDA level.

**Krishnendu Saha:** So adjusted for the one-time, it is profitable. Vinita, just a question. On the products, we think we would want to take up the market in the next year.

**Vinita Gupta:** Couldn't follow that question.

**Krishnendu Saha:** I'm not audible very much, right? Wait. Just a minute. Can you hear me now? This is better.

**Moderator:** Yes. Go ahead.

**Krishnendu Saha:** This is better. So how many products do you think that you will be taking off the market in FY '23 in the US?

**Vinita Gupta:** I mean we are putting the list together. But right now, we have three to four have been identified.

**Ramesh Swaminathan:** Already dropped 10 so far.

**Vinita Gupta:** From the portfolio, current portfolio

**Moderator:** We are going to take the next question, that is from Mr. Nitin Dharmavat. Okay. Next question is from Sameer Baisiwala.

**Ramesh Swaminathan:** How many people are online, if I may ask.

**Moderator:** It's 250.

**Vinita Gupta:** Oh my gosh.

**Ramesh Swaminathan:** Sameer, we can't hear you

**Moderator:** Sameer, can you just unmute yourself, Mr. Sameer?

Okay. We'll go to the next one. Next question is from Kunal Dhamesha.

**Kunal Dhamesha:** So, the first one is on the Spiriva. Where are we in terms of that approval? Have we got any information request or queries from the U.S. FDA?

**Vinita Gupta:** Actually, we are in a really good position. We have got feedback from the FDA that chemistry bioequivalence, PD, labeling is all fine. They are going to likely reinspect the facility before they approve, but everything else on the filing is fine.

**Kunal Dhamesha:** Okay. And second one on the -- I've heard the FTS word very frequently in this presentation. So if you can quantify how much FTS has impacted us in this year overall? And what is leading to such operational blocks, I believe, which would be leading to non- supply and then these kind of penalties. So, if you can quantify and where do we see ourselves on that front for the next couple of years?

**Ramesh Swaminathan:** So this has really been a bit of an embarrassment in some sense because we paid close to about $27 million during the course of this year itself by way of FTS. It's like this for the last couple of years. And if we were to -- if there were not to be there, to the extent we would have been much better off from a P&L perspective or from a bottom line perspective.

**Nilesh Gupta:** Ramesh, to clarify, there is obviously a significant amount of catch-up in that FTS as well, but I think it's now current to reflect whatever may happen only within the fiscal.

**Kunal Dhamesha:** Okay. I mean it sounded like that this was kind of a kitchen sinking quarter, but then we are also expecting the first two quarters to be similar. So again, the FTS issue and other issues are going to play in the quarter or we have taken a lot in terms of provision in this quarter?

**Vinita Gupta:** No, the FTS are normalized and even the losartan impact we took into the last quarter because we expect some failure to supply penalties due to the losartan recall. We expect the U.S. to be soft in Q1 because we noticed that at the end of the quarter, we had a good couple of weeks' worth of additional inventory at our customers, which they were going to draw down, and we saw that impact in April. So, we expect that this quarter is going to be soft.

**Nilesh Gupta:** But then Q2 onwards, it starts normalizing and then, obviously, late in Q2, Suprep and then other initiatives as well.

**Moderator:** Next question is from Tushar Manudhane.

**Tushar Manudhane:** Just again on Spiriva. I guess the facility was already inspected. So any specific reason that is triggering the reinspection?

**Vinita Gupta:** So the agency had to inspect also a device supplier in Germany. And so we are ready to -- we reinspected ourselves. We don't know for certain whether they're going to reinspect us, but they will -- they are inspecting our device supplier right now.

**Tushar Manudhane:** Good. So effectively, this is your response to U.S. FDA and the reinspection. Does the target action date of August 22 changes or that remains very much on track?

**Vinita Gupta:** I mean, hopefully, they don't need to reinspect us. If not, then I think we should be in a good position.

**Nilesh Gupta:** The date stands as of now.

**Vinita Gupta:** Yes. The data has not changed.

**Tushar Manudhane:** Got you. And just if you could clarify the FTS number for 4Q FY '22 in specific?

**Ramesh Swaminathan:** No -- sorry, in Q4, it would have been less than about $4 million.

**Tushar Manudhane:** And that is already factored out while giving EBITDA margin of 7.3% in the press release.

**Ramesh Swaminathan:** All of this is factored in the results. Yes.

**Tushar Manudhane:** No. I mean, is that adjusted for -- while giving the EBITDA margin of 7.3%.

**Vinita Gupta:** No

**Ramesh Swaminathan:** No, it's normalized. It's there in the EBITDA, but not the adjusted EBITDA. It's not normalized for that.

**Vinita Gupta:** Exactly

**Moderator:** Next question is from Hitesh Mahida.

**Hitesh Mahida:** So, just wanted to understand, I mean, with more than $2 billion sales, I mean why are we struggling with the single-digit sort of margins? And ex of Spiriva and Suprep, what sort of margins are we looking at? I mean, will there be an improvement there as well? Because at almost $700 million, $800 million U.S. sales, I mean we are struggling to break even in that U.S. geography

**Vinita Gupta:** Yes. So our struggle is really with the oral solids. With the oral solids, as we've talked about, Ramesh mentioned, Nilesh mentioned, we've had one pricing pressure, but second, also costs mounting from idle cost standpoint, from inventories like for the flu season products that we had additional write-offs in the year. Those are the inefficiencies. And what we're addressing is really the oral solid P&L.

When we look at our other platforms, when we look at inhalation, albuterol, Brovana and the like and our partnered products, we have really decent profitability on that front. It's really the oral solids that drag it down. So, we're very significantly addressing the oral solids through the optimization efforts that Ramesh mentioned.

**Hitesh Mahida:** As you had earlier mentioned, ma'am, we are looking at certain leadership roles. So frankly, because across geographies like US, India, finance, across those business verticals, we are sort of struggling now. So any sort of changes are we looking there?

**Vinita Gupta:** Actually, other than the US, I don't think we are struggling.

**Hitesh Mahida:** India growth is also sort of coming down.

**Ramesh Swaminathan:** No. I think we clarified on the India growth. And you'll see it over the quarters as well. We feel very, very good about our team in India and the growth that we have. You're going to get lumpiness across the sector for adjusting for Covid drugs over this period of time. But you'll see great normalization. I think in our peer set, there's possibly only one company bigger than ours that grew at a rate similar or a tad bit more than us. But in the top 10, I think we're number three or number four in terms of growth over a 10-year horizon, over a five-year horizon, even a three-year horizon.

**Vinita Gupta:** In terms of the leadership that both, Saion, you talked about in a question, I mean, we are going to have a major leadership change. Alok is going to be departing from the company. As you know, he was the Head of U.S. Generics, Biosimilars and Global R&D. For personal reasons, he has decided to leave the organization for the opportunities. And we have taken this as an opportunity to get closer to the business, both Nilesh and myself. We have a very strong Head of Commercial in the U.S., who started the U.S. business, who will lead the P&L from a U.S. perspective.

We felt the need and had already started a search for a Chief Scientific Officer for organization with a number of platforms that we have. Our biggest unleash for the organization is our pipeline delivery and platform performance, for which we identify the need of a very strong Chief Scientific Officer. So, we have a search ongoing for it. We have an Interim Head of R&D, Interim CSO, our Head of Portfolio and Pipeline. Sofia Mumtaz is our Interim Chief Scientific Officer.

And we've also created a very high-powered -- not high powered, in terms of level in terms of leadership, but a very strong project management office that reports into Nilesh and myself to map and to track all products from product selection to development, to filing and launch to ensure that we get the most out of our R&D investment. So multiple changes there on the -- related to the U.S. business that I felt was -- would be good to share with you.

**Moderator:** Yes. We'll just take last two questions. Next question is from Bhawna Agarwal.

**Nithya Balasubramanian:** Sorry. This is Nithya Balasubramanian from Bernstein. So Suprep, what is the brand size of the target addressable market?

**Vinita Gupta:** Something $200 million.

**Nithya Balasubramanian:** Sorry, I didn't catch that, if you don't mind repeating?

**Vinita Gupta:** $200 million.

**Nithya Balasubramanian:** All right. The second one on pegfilgrastim. What is the increment cost related to the commercial infrastructure should we expect in FY '23 and also on an annualized basis?

**Vinita Gupta:** It's marginal in FY '23. We hope to be able to -- if we get approved and can launch, we hope to really be able to get enough product into the market so that it pays for itself.

**Nithya Balasubramanian:** So breakeven is what you would target in FY '24?

**Vinita Gupta:** Yes. In FY '24 -- well, depending on when it gets approved, between FY '23 as well as FY '24 with pegfilgrastim in particular. I mean it should it pay for itself. Our strategy is a pretty lean model from a market access standpoint through a couple of channels that we've identified as ideal channel for us.

**Nithya Balasubramanian:** Got it. One last one. Did we hear you mention that Lucentis is a product for which you have a partner, who will commercialize the product in the US?

**Vinita Gupta:** We're going to commercialize it ourselves. We have channel partner that are ideal for Lucentis, ophthalmic clinics, channel partners.

**Moderator:** Last question is from Kunal Dhamesha.

**Kunal Dhamesha:** I think for India business, we mentioned that there is the lumpy nature of the tender business. So can you please quantify what's the tender business as a percentage of total India business for us?

**Nilesh Gupta:** I don't -- Ramesh, do you have the number? Otherwise, we'll have to take that one offline.

**Ramesh Swaminathan:** 400 -- are we talking about the GIB business, per se?

**Nilesh Gupta:** About India -- India part.

**Ramesh Swaminathan:** India, I don't recall.

**Nilesh Gupta:** It's a couple of INR100 crores in all in any case, but I don't have the specific number right now.

**Vinita Gupta:** We should report it separately.

**Nilesh Gupta:** We should report it such that it's easier.

**Kunal Dhamesha:** Okay. And on India business -- just one follow-up. On India business, we don't have any higher channel inventories anything. Because in response to Covid, a lot of companies' kind of pushed inventories. And now that there is no Covid, we don't have that situation, right?

**Nilesh Gupta:** So like I said, we would really want a player in the Covid sector. There were some write-offs that we already took, but obviously, nothing like any of the bigger players in the Covid therapy areas.

**Moderator:** Thank you very much.

**Ramesh Swaminathan:** Thank you very much for your guidance over the last several years, how do we end up and your support all the time. Thank you.

**Moderator:** Thank you so much for joining us. You can now exit the webinar as well.