“Lupin Limited Q2 FY2022 Earnings Conference Call”

October 28, 2021

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Moderator: Hello everyone. Welcome to Lupin Limited Q2 FY2022 Earnings Call. Please note, all participant lines will be in the listen only mode and there will be an opportunity for you to ask questions after the opening remarks. Should you need assistance during the conference call, please raise your hand from the participant's tab on your screen. Please note that this conference is being recorded. I now hand over the conference over to the Lupin management. Thank you and over to you Sir.

Kamal Sharma: Hello, Good afternoon and welcome to this earnings call. You have the results with you. I know you have lots of questions. I straightaway hand it over to our CFO, Mr. Ramesh Swaminathan to explain the financial details. Then we'll open the floor for question and answers. Over to you, Ramesh.

Ramesh Swaminathan: Thank you Dr Sharma and welcome back friends. Hope that you and your family are keeping fine. I'll begin with the commentary on the sales. Sales for Q2 FY22 are INR 40.03 billion as compared to INR 42.37 billion in Q1 FY22, a 5.5% degrowth and 5.9% growth as compared to Q2 FY21 sales. You'd recognize that adjusted for NCE licensing income in Q1 FY22, the QoQ growth is 3.6%, whilst the YoY growth is 5.9%. U.S. sales grew by 7.2% sequentially, at US$184 million in Q2 FY22 as compared to US$172 million in Q1 FY22 and grew by 2.2% YoY as compared to US$180 million in Q2 FY21. The QoQ increase was driven by the increase in the sales of our respiratory franchise led by incremental sales of albuterol and full quarter sales of Brovana AG.

The India region saw a QoQ degrowth of 5.7% due to higher Covid second wave driven sales in Q1 and 16% YoY growth on the Covid impacted base in Q2 last year. India region sales were higher than the market growth rate across both the acute and chronic therapy areas, but were impacted by higher salience of chronic therapies, which grew at a slower pace. For API sales, QoQ growth at 8.9% was driven by higher quetiapine sales to Kyowa. Core API business was flat QoQ but down YoY due to lower volumes and demand. Sales for EMEA grew by 33.3% QoQ and 6.9% YoY due to higher sales across all markets as Covid restrictions are gradually easing. We also launched Luforbec i.e. generic of Fostair in Q2 in the U.K. market. Sales for growth markets grew by 4.9% QoQ and 19.6% YoY due to continued recovery in almost all markets - Mexico, Philippines and Australia.

We have had some exceptional items this quarter, as you would recognize. One-time costs related to U.S. specialty restructuring of about INR 326 million, of which INR 200 million is under the manufacturing and other expenses and about INR 126 million in employee benefit schemes. We provided for the Glumetza antitrust class action suit and that has been included in the results. There is also the impairment expense of INR 7,077 million that's essentially related to the Solosec IP.

The normalized operating EBITDA excluding Forex, other income and one-offs - that's the NCE income in Q1 and specialty restructuring in Q2, moved up from 14.3% in Q1 FY22 to 14.9% in Q2 FY22. A positive impact of lower R&D, employee benefit expenses were offset by the fall in gross margins as well as an increase in SG&A expenses largely due to promotion, travel and plant operating expenses as well. Within Gross margins, royalty/profit-sharing expenses on certain in-licensed partnered products have been reclassified from Q1 FY22. On a comparable basis, the gross margin adjusted for such change would have been 62.7% of sales in Q2 FY21. Q2 FY22 gross margins was 59.4% as compared to Q1 FY22 gross margins adjusted for NCE licensing income of 60.5%. This is mainly due to the decline in API margins and offset by positive impact of higher U.S. sales and lower GIB sales. YoY drop from 62.7% to 59.4% is on account of impact of higher royalty expenses, lower U.S. margins offset by positive revaluation impact. Employee benefit expenses is expected to normalize around 18%. We expect R&D to be around 8 - 8.5% going forward. The ETR is on expected lines and is expected to be less than 30% for FY22.

With this, may I open the floor for the discussions.

Moderator: Thank you. We will now begin the question and answer session. Anyone who wishes to ask a question may raise your hand from the participant's tab on your screen. Participants are requested to use headphones or earphone while asking a question. Ladies and Gentlemen, we will wait for a moment while the question queue assembles. We request you to please introduce yourself before asking the questions.

First question is from Mr. Kunal Dhamesha.

Kunal Dhamesha: Thanks for the opportunity. Firstly, on the target that we had set in the last quarter in terms of U.S. revenue growing to around US$ 200 million per quarter run rate in second half of the FY22 and EBITDA margin reaching the 17% to 18% level. Are we still on track to achieve that?

Vinita Gupta: We're on track to achieve over US$ 200 million a quarter in the second half. On the EBITDA margin, at this point, we believe that we're going to improve our EBITDA margin for the second half to 16% plus level.

Kunal Dhamesha: Sure. If I look at the gross margin closely this quarter, our U.S. has ramped up and ramp up would have been on the back of albuterol. So, is it that albuterol is now a lower gross margin product for us? It might be accretive on EBITDA margin, but on gross margin, is it a margin dilutive product?

Vinita Gupta: Actually, the growth has been both albuterol as well as Brovana AG. We have 55% share of the Brovana market. At this point, it's a material product for us. The gross margin on Brovana AG is lower than our average gross margins for the U.S. business. Albuterol is a high gross margin product. Brovana AG and

all our partnered products, are a nice complement to our internal portfolio and also accretive at the EBITDA margin levels.

Moderator: Thank you. Next question is from Ms. Damayanti Kerai.

Damayanti Kerai: Thank you for the opportunity. My first question is on your specialty restructuring in the U.S. After restructuring, what kind of cost savings you expect on a sustainable basis? And now what is the team size for Solosec? And in general, what is your specialty strategy for U.S. market going ahead?

Vinita Gupta: With the restructuring, we are going to have more than US$15 million annualized savings starting Q3. What we have retained is a skeleton structure comprised of market access as well as distribution. In the last couple of years, we have really built enough awareness on Solosec, and are at this time planning nonpersonal promotion of the product until we can get to a point where it justifies to really have a dedicated headcount visiting the physician's office.

We now believe that with the current nonpersonal promotion strategy, we should be able to at least hold the current scripts at where they are, if not grow. Likewise, we have multiple pipeline programs that we have developed on the women's health front. We are pretty far along in getting those pipeline programs funded by partners. So, in effect, what we have done is reduce the current burn from specialty but retained the optionality to build specialty in the future. We'll really look at how things evolve on our overall business. The focus in the near term is to execute on the generic front, which is the biggest part of our growth for the company as well as the business in the U.S. and have the optionality to build specialty in the future.

Damayanti Kerai: Ma'am, one clarification on specialty pipeline assets going ahead, you mentioned optionality. So, are we going to do all products in partnership rather than taking all expenses on our books?

Vinita Gupta: We are basically working on getting funding partnerships on the pipeline.

Nilesh Gupta: Just to clarify, if there are commercial assets that we like, which would be accretive, obviously that would not be a partnership. We would make investments if we found the right assets. But the focus right now is on execution on generics and India business, and getting both of these to a very solid position.

Damayanti Kerai: Okay. And my second question is, can you provide update on key respiratory pipeline assets?

Vinita Gupta: Beyond the products that we have in the market i.e. albuterol and Brovana AG in the U.S., gFostair in the U.K. which is launched very successfully, the largest one in the near term is gSpiriva, where we've entered into a

settlement with BI on the litigation front. That's really taken away the litigation risk. We've got a very favorable date that we will look forward to disclosing in the future. We are working right now towards getting the product approved.

We recently responded fully to CRL that the agency had raised. Expect to get approval in the next calendar year. So, that should be a material growth driver in the near future. We continue to make progress on other pipeline programs like gDulera, and we have gFlovent, gSymbicort, gQvar in our pipeline. We also have the next wave platforms - ellipta device that we have developed in-house and are developing programs on the device. So, really a rich pipeline of inhalation products in the years to come.

Moderator: Thank you. Next question is from Mr. Anubhav Aggarwal.

Anubhav Aggarwal: Just one question, Ramesh sir, clarity on other operating income which was pretty high in this quarter at INR 879 million. We were doing about INR 250 – 300 million so far. So, was there some one-off in this quarter in the other operating income?

Ramesh Swaminathan: Yes, there was a litigation avoidance component.

Anubhav Aggarwal: So, what's the usual run rate, should we still continue to build about INR 250 - 300 million for the next 1 or 2 quarters?

Ramesh Swaminathan: Yes, that should be pretty okay.

Anubhav Aggarwal: Okay. You talked about in June, after the Board meeting, you mentioned that you want to get into digital health business, and recently you started the diagnostic arm as well. Can you talk about what you plan to do in digital health piece of the business? Secondly, in diagnostics in next 3 – 4 years -- are you expecting that to be INR 2-3 billion kind of business? Anything you can talk about?

Nilesh Gupta: Both the digital health as well as the diagnostics are not the dominant part of the India story. The India story very much is prescription branded generic products, even generic-generic products, and to a lesser extent, OTC products. There's a full diagnostics rollout next week onwards. We will be commercial, we'll be operational. We believe that this is a great adjacency to our prescription business. We'll see how it shapes up. Premature to give guidance on where the numbers will head. But obviously the numbers have to become meaningful. We believe that this piece is big enough, wide enough for us to be able to grow.

On the digital side, I think there are many initiatives that are underway. I think we're still looping them all together. Obviously with the Covid period, we moved to digital detailing to doctors, that continues even now. Each representative would make a digital detail to a doctor in addition to the requisite physical ones as well. There is a tele consult platform that we're

launching as well. There's a whole bunch of initiatives there. Again, premature to loop all of it together and say where does this go from a revenue perspective.

Anubhav Aggarwal: Okay. That's helpful. Vinita, in terms of the specialty business, the US$15 million you take out, but what's remaining there? Is it like US$5-10 million kind of number on an annualized basis, which you are still spending there, or not even that much?

Vinita Gupta: It's around US$5 million to really keep the distribution and access going.

Moderator: Thank you. Next question is from Mr. Surya Patra.

Surya Patra: On the albuterol side, can you clarify whether the full benefit of albuterol in terms of 18% - 20% kind of market share what you have been indicating, that is visible in the current quarter, means Q2 number?

Vinita Gupta: Yes. It is ramping up. In the last couple of IQVIA data points, we are at 16% share of the entire market, 20% of the generic market. We are the third largest player now in the albuterol market, and it is ramping up. We've seen some growth for albuterol QoQ. You'll see more so in Q3 and Q4.

Surya Patra: And in terms of R&D spend side, if you can give some clarity here since now there is a kind of a revised thought process in terms of spending, in terms of asset allocation about the specialty business. So, what would be the R&D spend mix and outlook for that, considering specialty and generic?

Vinita Gupta: It should be at a similar level as the first half, ~INR 3.5 billion a quarter. As Ramesh said, it should be 8.5% of sales for the year. As I mentioned on the specialty programs, we're getting them funded. We were able to get very lucrative funding for it. The primary focus on the R&D front is a complex generic portfolio, other limited competition oral solid portfolio and biosimilars. I'd say the bulk of the investments on the R&D front are geared towards complex generics and biosimilars. On the oncology NCE programs, we're pursuing a plan that will help us spin it out.

Surya Patra: Would we see any kind of moderation in the R&D spend on an absolute number moving ahead?

Vinita Gupta: Yes, we would see in the next couple of years, the R&D as a percentage of net sales coming down. I think we should be able to maintain this 8% level and then bring it down as we grow our revenues. But it should be at a similar level going forward based on the pipeline that we are pursuing.

Nilesh Gupta: Even as an absolute number, obviously we have ended at this level, and the intention like Vinita said, in H2, is to hold it at the same level as what was for H1.

Surya Patra: Just last one question on the diagnostic initiative. What is the strategy that we are thinking? Or what is the kind of a strength or synergy that we are kind of driving from the existing business for this new initiative? And what would be your thought process here, whether being a new entrant, you would be focusing more on the cities, metros like that, where the competition will be higher, or even from the day 1 like try to capture as much as of the Tier 2 cities as well? Or what would be the strategy here?

Nilesh Gupta: First of all, I want to be candidly clear. I would not build too much of expectation around the diagnostics foray. That is something that we are starting, it's something that we will get into. I'm sure we'll make our share of mistakes. The core focus in India very clearly, I'm reiterating is the prescription business. We have always grown 20% to 30% more than the market, and the goal is to continue doing that on the Rx side of the business. The diagnostic foray is a full rollout. It is a national play. But it will be calibrated, it will be stage gated. There are key metrics that have to be met as we decide how and if to scale it up as well. I would wait for it to roll out. We'll be more than happy to come back and talk about it as it gets more meaningful.

Surya Patra: Sure, sir. Just on the margin outlook front, if you can talk something more about because there are so many changes in the business model that we are anticipating and there is a conscious effort also to improve the profitability of the consolidated number and all that. So, what triggers that you are thinking that should be taking Lupin as a profitably growing company going ahead?

Ramesh Swaminathan: Last year, we did grow our margins from 14.6% to 16.6% to 18.6% and eventually to 18.8%. When we started this year, we expected the tempo to be kind of sustained. Unfortunately, there were a couple of setbacks, the first being famotidine. There was more than expected competition with 2 competitors coming in, whilst we expected only 1, and that too sometime later. There's, of course the move away from spot sales for albuterol to more long-term contracts. Further, there was an element of FTS. All of this were setbacks and it did impact our gross margins. We also explained, the accounting treatment change for partnered products.

But having said that, there's tremendous commitment to maintenance of initiatives on reducing costs which includes procurement excellence, route to synthesis and all of that. More importantly, I think one of the issues that we've faced is essentially not being in high realization products. As you would know, we've got a pipeline. We've got a plan to bring a lot of those products together over time. Continuing on the same front, there is a lot of rationalization happening when it comes to the sales force, productivity out there and when it comes to the R&D spend and the like. Apart from that, we spoke last time around also on restructuring endeavors, which includes, in fact the NCE spinoff and a host of other things, including specialty and the like.

So, there is the march towards recognizing the fact that we are behind the curve when it comes to the EBITDA margins. It's a march that is on and we are very confident and committed to getting to the 20% mark, but we wouldn't like to put a timeline to it, but it will certainly happen in the next few quarters. And for sure, you would see the incremental things coming through in Q3 and Q4 also. As Vinita and Nilesh committed, it could be above the 16% mark in the quarters to come.

Moderator: Thank you. Next question is from Ms. Nithya Balasubramanian.

Nithya Balasubramanian: This is Nithya from Bernstein Research. So, my first question is on the India market. If you look at IQVIA data, unfortunately, chronic therapies like diabetes or cardiology are showing slightly lesser growth than what we're used to seeing. Given Lupin's exposure to chronic therapies, are these numbers something that you are seeing in the market as well? Or is your covered market growing faster than that? And is there any likely impact -- any hypothesis on why we are seeing this slowdown in growth?

Nilesh Gupta: Internally, first of all, our growth in Q2 was 17.4% versus the market reported growth of 15.4%. Both on the acute and the chronic side, we grew faster than the market. The IQVIA reflection is what it is. The acute side is really what has driven growth through the Covid period. It continues to be an important part. It's coming down, it came down in Q2, it's going to come down even more in Q3 to Q4 as well. We made a conscious decision to focus on chronic therapies, probably some 20 years ago. I think its reaped rich rewards. In our entire peer set, the amount that we draw from chronic is the highest. We believe that means sticky, sustainable growth. Our goal very clearly on the chronic side is to grow 20% - 30% higher than the market growth rate.

There is a slowdown, especially with the Covid period, there was definitely a slowdown. For example, respiratory was a terrible slowdown last year, it's come back with a big bang at this point of time. Diabetes seems to be slow at this point of time. We believe that it's possibly a function of patient footfalls. Again, patient footfalls are back, so we would expect for this to pick up. We would continue to do 20% - 30% more. I think the hypothesis remains the same, the focus is there on the chronic therapies. There are other chronic therapies where we're not as strong. For example, in CNS or in gastro, our goal would be to build in those spaces as well. They are all great growth areas, still an extremely fragmented market and a lot of room for growth

Nithya Balasubramanian: Got it. My next question was on your biosimilars pipeline. If you can give us an update on your filing and the pipeline? And are you looking for, again external funding by partners? Or will this be funded through your internal R&D?

Nilesh Gupta: We're pretty happy with where we are with the biosimilar portfolio to date. Funding has been a concern and it has been a part of our story so far. Our lead

product was Etanercept, which is approved in Japan and Europe. One day it will come to the U.S. when the patent expires. Our first lead product to the U.S. is peg-G, which we filed. It's going through the review process nicely. We don't see any showstoppers right now. A key milestone is going to be a likely inspection of the facility, there's some to and fro on when that might happen. The next product is ranibizumab, which is in development. There's a global clinical trial underway, ran slower on account of Covid, but again we hope to ramp that up going forward.

There are 2 - 3 new products which are in the earlier stages of development in the pipeline as well. With the way that Lupin is able to fund this, obviously there is a constraint on how many of these projects we can finance. Vinita talked last quarter about a spinout of, one was the oncology, the second was likely the biosimilars, the third was also taking care of the specialty expense. So, we've done the specialty expense. We're on the way on the oncology spin out as well. The biosimilar spinout is certainly something that stays on the table as a discussion item. We do hope to be able to action that. I think that would free up the way for a lot more portfolio expansion, not necessarily waiting for a funding partner to tie up on a project-by-project basis and it will give a lot of latitude to development. But in the meanwhile, we cherry pick. We do 2 or 3 products at a point of time, likely 1 or 2 products in the clinic.

At any point of time, we have great capability on the R&D, manufacturing, drug substance, drug product side, on the regulatory side. There is great capability to be used globally as far as biosimilar is concerned. It is going to be a good growth opportunity. But I think the financing story has to still play out.

Nithya Balasubramanian: A quick follow-up on pegfilgrastim. So, assuming you secure an approval in FY23, will you also be investing then in building a commercial infrastructure to push the product in U.S. and wherever else you file it?

Vinita Gupta: Yes. So, the major opportunity is really in the U.S. with pegfilgrastim. It was very late in Europe with that product. We have other products that we are still focused on Europe, but the opportunity is really in the U.S. We will definitely look at investments to effectively commercialize and start our biosimilars business in the U.S. effectively and really calibrate it versus the opportunity.

We also have a follow-on for pegfilgrastim, the Onpro biosimilar. We're going to have both pegfilgrastim as well as the Onpro biosimilar. There's going to be a timing gap. We will assess whether it make sense to try to club them together to be able to leverage the commercial investment or launch pegfilgrastim ahead of the on-body product. We hope that we have the opportunity to launch next fiscal year. Like Nilesh mentioned, it's going to depend on the inspection. The agency has already informed us that they will have to inspect the site. We'll wait for that milestone to pass and then determine the right timing to set up commercial infrastructure.

I'll also say that the commercial infrastructure for biosimilars has synergies with our injectables institutional portfolio. We are simultaneously building our injectables portfolio as well, both internally through our pipeline as well as through partnerships, through in-licensing. We'll determine the exact timing to be able to really get an effective portfolio as we enter the market, both with pegfilgrastim as well as the institutional products.

Moderator: Thank you. Next question is from Mr. Sameer Baisiwala.

Sameer Baisiwala: Good evening everyone. Vinita, just to be sure, so are you still looking for Spiriva launch in the U.S. in fiscal '23?

Vinita Gupta: Sameer, we just had a settlement where we agreed not to disclose the date until the product approval. As I mentioned, it continues to be a material growth driver in the near term. We don't change our guidance on the product from what we have shared so far.

Nilesh Gupta: It's a very favorable date. We recognize that this is a clear part of our inhalation build over the years to come. Obviously, we were not going to compromise that.

Vinita Gupta: We were very pleased to really take the litigation risk out.

Sameer Baisiwala: Excellent. Second is on pegfil onpro filing. Is this a separate dossier, separate clinical trials? And what exactly is the status on this?

Vinita Gupta: Yes, it's undergoing development. It's going to be a supplement on to our pegfilgrastim product, but there are additional studies that we have undertaken. We expect to file it in the next fiscal year, fiscal year '23.

Sameer Baisiwala: Okay. So, it is at least about 18 months behind the regular pegfil?

Vinita Gupta: Yes. You're right.

Sameer Baisiwala: Great. The other question is on the 20 exclusive FTF opportunities, the ANDAs for which you have filed. So, of these 20, what could be the launch expectation over the next, say 18 months?

Vinita Gupta: We have a couple of the first to files. The major ones - we've already talked about gSpiriva, we've talked about Pegfilgrastim, we have gSuprep that we expect September next year. So, we have a couple of others next year as well, but these are the major products for next year.

Sameer Baisiwala: Great. One final from my side. What's holding back Revlimid settlement? And are you still on course for 2022 launch?

Vinita Gupta: We are still working through our strategy on settlement. We'll determine what makes sense from a risk perspective. We're still under negotiations. I can't really talk more about it.

Moderator: Thank you. Next question is from Mr. Harith Ahmed.

Harith Ahmed: On generic ProAir, the other approved generic that left the market sometime last year. Will you be able to give some sense of when they're likely to return? I see that their ANDA is currently under discontinued status.

Vinita Gupta: We haven't heard of any new developments with their product. We know that the site where they were manufacturing the product also had an issue recently with the agency. So, we think that it's at least not in the next 12 months. We don't see the competitive dynamics on albuterol, ProAir changing anytime in the near future.

Harith Ahmed: Okay. On generic Spiriva. I see that there's been some switch from the DPI version which we filed, to MDI version which was launched more recently. So how should we think of the opportunity by the time we launch in terms of the opportunity that is left in the DPI product?

Vinita Gupta: Still a material opportunity despite the switch and more importantly the expansion of the market. Respimat also expanded the market for the product. Certainly, it's another pipeline program for us. But we still look at the HandiHaler, the DPI as a material opportunity for us in the next couple of years.

Harith Ahmed: Okay. Then last one on biosimilars. So, what percentage of our R&D will be into biosimilars? And could you also share the gross block related to our manufacturing facility for biosimilars?

Vinita Gupta: Less than 10% of our R&D spend is in biosimilars.

Ramesh Swaminathan: The gross block is less than INR 5 bn at this stage, much less than that.

Moderator: Thank you. Next question is from Mr. Nitin Agarwal.

Nitin Agarwal: On the U.S., you mentioned a portfolio of inhaler products which are under development. Now Spiriva, obviously you guided to. But for the other products, what would be the tentative broad timelines that we can look at for the market formation?

Vinita Gupta: After gSpiriva, gDulera is around the same time. We're working with the agency right now on gDulera. We have gQvar which is pretty far long in development. Then behind that, we have products like gSymbicort and gFlovent. After that the Ellipta products and Respimat products.

Nitin Agarwal: Right. So, will we have a position where we probably have -- maybe launches literally coming in every year, starting next year onwards. So, is that a fair way to look at? Or the way the development pipeline is there, we probably will have a little bit of a lag before the rest of the pipeline begins to kick in post-Spiriva?

Vinita Gupta: We are hoping that we should be able to get one a year after Spiriva. I think we should meet that position given the status of our pipeline

Nitin Agarwal: That's great. Secondly, a little bit more near term, with Spiriva, Suprep that you mentioned, it starts to come through September of next year. Over the next 3 to 4 quarters, how should we see the U.S. business? We've talked about a scale of US$200 million. What is going to drive that as we go forward?

Vinita Gupta: Really the ramp-up of albuterol is a big one, which we've already started seeing in the last couple of weeks, months. Brovana AG continues to be a big opportunity, given our strategy to launch a few weeks before the rest of the generics. They certainly continue to be good growth drivers. Our team has worked very hard to win back some of the business that we lost on the baseline through the supply challenges that we had in the last year through Covid. We lost a good number of products and market share, if you recall, that we talked about in the last quarter, especially with Express Scripts breaking out of WBAD. Our team has done a really good job in building the baseline back again.

So, you'll see a better baseline. The older in-line products and then really ramp up of albuterol and Brovana AG for our contracted volume, contracted customers and then executing some of the new product launches. We have a few like Sevelamer, we expect to launch fairly soon. We have a couple more products that we'll have the opportunity to launch. Then we have our partnered products, for which I know we don't like the impact on the gross margin, but on a net basis, significant contribution to our profitability. We recently launched the AG to Duexis, and we continue to work on our partnered portfolio. We have a very rich pipeline of partnered products that we are working on right now that, hopefully, we should be able to announce soon that will again help us grow our revenues as well as bottom line.

Nitin Agarwal: And if I can squeeze on associated point on that. You talked about getting market share back in the in-line products. Last six months, there has been a lot of talk about the resurfacing of the pricing pressure in the U.S. How is that environment shaping up? Is there any easing off? And when do you see things sort of coming back to a more normalized behavior on the pricing front?

Vinita Gupta: It's hard to predict. Every time we say something, and we correct ourselves the next quarter. I'd say that the majority of our peers are talking about pricing pressure in the mid to high single digits. We continue to see that. It's

very important to be able to continue to work on cost saving efforts on the baseline, the in-line products and execute on the new product launches.

Moderator: Thank you. Next question is from Mr. Shyam Srinivasan.

Shyam Srinivasan: Just first one is on this Glumetza antitrust settlement. So, is this the end of it, in terms of are there other litigations that are still there? Or at this point of time, we think we have provided through this settlement for most of those claims?

Vinita Gupta: Yes. We believe we have put it behind us.

Shyam Srinivasan: Got it. And Vinita just to step back and look at the history of Glumetza, it's been a name that's been associated with us. Just what are some of the learnings out of this entire process? I think given that litigation has been especially pay-for-delay and other such litigations, how should we look at pricing our products in the U.S. specifically?

Vinita Gupta: I mean, when you think about actually the execution, when we launched the product, I wouldn't do anything differently. From our perspective, we had got an early date to launch, when we were in a situation in 2012 that we were going to lose the patent case. We got a negative Markman hearing and were about to lose the patent case and got a date before the patent in question, which obviously brought a generic early to market. In the interim Valeant raised the price of the drug and increased the price 10x, so it became a very different opportunity. At the same time, we bought US$0.5 billion worth of savings to the U.S. customers and government and payers. So, to be honest, on the commercialization front, I wouldn't do anything differently.

Then would we do a no AG kind of settlement? No. That changed from 2012 to even 2014. In 2012, when we did the settlement, AGs were considered uncompetitive. They were considered as that they would cut the exclusivity of the first to file. Then there was a case that changed it a couple of years after. I think the learning is really on the settlement front, we wouldn't do a no-AG settlement anymore. But from a commercial perspective, I wouldn't have done anything differently.

Shyam Srinivasan: Got it. That's very helpful. The second question is on capital allocation. Just in terms of we have reduced our exposure to the U.S. spec business. It looks like we're investing in biosimilars. So just want to understand what the capital allocation priorities are for us. If you could highlight in either areas, in geographic areas or product segments that Lupin will probably invest for the next 3 - 5 years?

Vinita Gupta: Maybe I can start and then, Nilesh will add to this, Ramesh as well. Our priorities are very clear. At this point, our base business, the U.S. generic business, complex generics, biosimilars, of what we believe a very high-

growth, high-margin business in the future is a big priority for us. India is a big priority for us. Leveraging our portfolio across other geographies, the inhalation platform, the biosimilars have very strong potential across our other key geographies, Europe, Australia, Canada and the like. So, leveraging the portfolio and trying to really figure out what's the best way we can get the full impact of our platforms across geographies is the other major area that we are investing into.

Nilesh Gupta: If I can add. I think the amount of capital that we're allocating is coming down a little bit. Certainly, we see the reason to moderate in the U.S. Vinita already talked about specialty. But even on the generic side, you can see that the R&D investment is coming down. The intention would be to keep it there, focused on the complex generics and biosimilars. We believe that those are incredible growth opportunities. We believe that the capital that we allocate to the generic business in the U.S. has to come down, and we are taking the right steps towards that. A small portion of that will go into investing into markets like India, whether it's R&D or manufacturing.

I think there is a very conscious capital allocation change, which is happening. There was a period where we were very heavily weighted towards generics in the U.S., that is moderating a little bit and bringing back more focus to India and in terms of also maximizing our portfolio globally. Ramesh, do you want to add?

Ramesh Swaminathan: Yes. I think both of you have articulated our strategy pretty well. You'd recognize that money should flow where the yield is going to be the highest. From that perspective, the endeavor on a lot of the organic part is on the complex and differentiated products. We would be calibrated in terms of our evaluation of the risk itself and where we believe the risk is very high, we would partner with the financial partners, taking away the risk element from the overall risk score itself.

And if your question is directed towards M&A. We've learned our lesson and to that extent, any aggression on that score would be very heavily debated and we would view it accordingly. On the newer ones that I think have been raised in this call, diagnostics and digital, the factors, as Nilesh very clearly articulated, it's going to be baby steps in that direction. The major theme is going to be on the existing business itself. We would take a very calibrated approach in the way we allocate capital towards that and watch out for returns before we start investing more in that.

Moderator: Thank you. Next question is from Mr. Prakash Agarwal.

Prakash Agarwal: Just one clarification. I just wanted to clarify if I heard that right that over 16% margin, was it for H2 or fiscal '22?

Ramesh Swaminathan: For H2.

Prakash Agarwal: Okay. What is the reason for the second reset? I mean last quarter, we had talked about this famotidine pricing pressure, reclassification, etc. So, despite we talking about entering albuterol long-term contracts from Q3, which is incremental sales coming through, specialty costs coming down. So, all these is incremental that should add up? So, what has really changed versus last quarter that we are taking another 100, 200 basis point reset?

Ramesh Swaminathan: There are several moving parts. You would also appreciate that material prices, and in a general sense, inflation seems to be raging across every part of the globe. We would like to be prudent, in terms of our estimation of the way margins should pan out. You would recognize that there are issues around, KSM imports from China, for example the pen G prices are close to about US$25. Not so long ago, it was US$8 and moved to US$12 and now US$25. All of this obviously has an impact. Our ability to pass on to the customers, to the channel partners is something that we need to gauge. All of these would actually cause us to be a little more prudent in our outlook towards things.

Vinita Gupta: If I can add to that, Ramesh, the other piece, especially related to the U.S. business is the flu season products. We have pretty much taken the flu season products out from our estimates for the second half. We really don't know how it's going to pan out. We're not seeing any uptick right now in products like Tamiflu or the Cephalosporins. We have idle costs in those facilities. We hope that will change. We're hearing that in December, we should see a severe flu season, but it's yet to be seen. We are not seeing it in the customer forecast and estimates or the buying pattern. So, the adjustment is on the business front on one side, the inflationary pressures on the other side like Ramesh mentioned, about the flu season products, which are impacting both our U.S. business as well as our API business.

Prakash Agarwal: Second one is on the U.S. FDA. So, we had couple of visits, I understand, and then there are some repeat observations. So, what is the current status? And the view that we take that by when do we start seeing some resolution?

Nilesh Gupta: Somerset, we've talked about that in the past, so I wouldn't go back there. Goa is obviously relatively fresh. We had 7 observations. None of the observations were characterized by the FDA as a repeat observation, although there are obviously some commonalities that we see with some of the observations. I shared earlier today that we feel that the observations are very readily addressable. We in our first update would address 6 out of the 7, and the last observation would take maybe a month or 2 more. But we feel very good about addressing these observations comprehensively for Goa as well as for all of Lupin. I do think that we are moving ahead. I don't like the fact that we had 7 observations, but like I said, these are very addressable. We're very conscious that we have to demonstrate with outcomes as far as what we do on the regulatory side. So, we're hoping that we should be able

to close the Goa inspection successfully. We're ready for inspections at our other sites like Pithampur and Tarapur. FDA has now sporadically started inspections in India. Obviously, these sites will get inspected at some point in the next few months or quarters to come.

Prakash Agarwal: Okay timelines for you to close out and get approval?

Nilesh Gupta: Like I said, in the next few months, the next 2 -3 months, we expect to be able to close out all the observations, undertake all our actions in line with all the observations that we had. Then it goes back to the FDA to make an assessment. There is obviously a process within the FDA to follow. Hard to predict that accurately. But in the next 3 to 6 months, we should know well on where the site resides in the eyes of the FDA.

Prakash Agarwal: Okay. Is Spiriva linked to Goa or Pithampur.

Nilesh Gupta: No. Spiriva is from our inhalation facility in Pithampur Unit-3. The FDA has been to that site. We have albuterol from that site. We have filed some of our derm products from that site. They've been to that site for Tiotropium also in the past. It is completely unconnected, and that site has had a pretty solid record.

Prakash Agarwal: That's great to know. And last one on the injectable, complex injectable that Vinita has alluded to. So, in the past, we had partnered with one of the players, ForDoz -- where are we on the development stage?

Vinita Gupta: Yes. We're making progress on the clinical development, and we were expecting to file it this fiscal year, and I think it's on track to file gDoxil this fiscal year and gAmBisome in the next fiscal year. Apart from that, we also have our own first depot product risperidone in the clinic. @e are in recruitment there. Have made progress also on the peptide products. We have glucagon that we should be in a position to file this quarter, our second peptide product. Really making progress across the complex injectable pipeline.

Prakash Agarwal: The second half fiscal '23 is what we last said that you'd start seeing some approvals. Are we on track on that? Or there might be plus/minus on that?

Vinita Gupta: We should.

Nilesh Gupta: Yes. Absolutely. We're also filling about 3 to 5 ANDAs out of our Nagpur facility and those are the ones that you'll start seeing coming in from FY 23.

Moderator: Thank you. Due to time constrains, we'll take the last question from Mr. Sameer Baisiwala.

Sameer Baisiwala: The question here is on Fostair and Enbrel. Do you think these have the potential to become sizable? I know what that is, maybe US$50 million per annum. What's the timeframe that you're looking for?

Vinita Gupta: gFostair certainly has a significant potential, Sameer. We've seen really good reception to the product in U.K. and believe that it will be a very strong double-digit product in the U.K. next year. Then we launch in the other European countries through our partners. So, certainly has the potential of US$50-plus million. I think the build on gFostair is in the next 2 to 3 years, just given the patent expiries across the different countries and the time it takes to build up, because it's more like a branded buildup as opposed to a pure generic.

And bEnbrel, Mylan is launching in other countries right now. They recently launched in France. They're getting ready to launch in other countries as well. I think that in the next two years, bEnbrel should be in a very good place. I don't know about US$50 million, but certainly strong double digit between US$20 - 30 million.

Sameer Baisiwala: That would be Lupin's share?

Vinita Gupta: Exactly, yes.

Sameer Baisiwala: Okay. Great. The other question is on diagnostics. Nilesh, is it a question of FOMO, fear of missing out, they get 20x sales, you get 20x earnings? What's really behind this?

Nilesh Gupta: I think there was a very conscious decision to pursue adjacencies in India. India is a market that we know best. We have a very strong position, especially in some therapies, we have a very solid position. The idea was, how do you leverage that? Obviously, you do everything that you can from an Rx perspective, from an OTC perspective. We feel that there is a hook for diagnostic. We feel that there is a hook for digital health as well.

Honestly speaking, time will tell. It's different from what other people have done. I think there's a great first mover opportunity here. We're going to ramp this up quickly. But like I said, it's going to be calibrated, it's going to be stage gated. It's never going to be the dominant story. The story is the prescription story that's already INR 60 billion. It's going to be INR 100 billion in the next five years. Everything else fails in comparison with that from a size growth perspective. But we see these as adjacencies that can really help build. Create much more touch points with doctors, much more touch points with consumers. Honestly, keep us at the front end of things as far as India is concerned. I think the story will unveil in the next couple of years, and we're looking to make it a very nice story of Lupin in India.

Sameer Baisiwala: Sure. We'll wait for that. But just a related question. Can this be a big margin drag, something that we are trying very hard to lift over the next say 2 to 4 quarters?

Nilesh Gupta: Absolutely not. First of all, this is all consolidated within the India business. We are making sure that, that business in itself keeps providing the lift that it has provided in the last few years as well. We would absolutely not do anything to drag down margin. We understand that our margin is well under anything that we had in the past and well under our peers as well. Our 1 goal is to shore up that margin in H2, into the next year firmly to the 20% and then start getting back to being leaders of the pack.

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

Kamal Sharma: Thank you very much, and I hope you have the clarifications for your questions. We hope to see you in the next quarter again. Meanwhile, take care of yourselves and your families as well.

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