



May 25, 2021

✓ **BSE Limited**

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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 FY2021 Earnings Conference Call.

Pursuant to Regulation 30(2) read with Schedule III Part A Para A(15) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Q4 FY2021 Earnings Conference Call held on Thursday, May 13, 2021.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,
For LUPIN LIMITED

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

Encl.: a/a



“Lupin Limited Q4 FY2021 Earnings Conference Call”

May 13, 2021

MANAGEMENT:

- **DR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**
- **MS. VINITA GUPTA – CEO, LUPIN LIMITED**
- **MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED**
- **MR. RAMESH SWAMINATHAN - EXECUTIVE DIRECTOR, GLOBAL CFO AND HEAD CORPORATE AFFAIRS, LUPIN LIMITED**
- **MR. ARVIND BOTHRA – VICE PRESIDENT, HEAD INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**
- **MR. VISHAL RATHI - VICE PRESIDENT, CORPORATE FINANCE, LUPIN LIMITED**



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Moderator: Hello everyone and welcome to Lupin Limited Quarter-IV and Financial Year 2021 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 participant's tab on your screen. Please note that this conference is being recorded. I now hand over the conference over to Lupin management. Thank you and over to you Sir.

Kamal Sharma: Hello, Good evening. My name is Kamal Sharma. I have with me my colleagues - Vinita Gupta, Nilesh Gupta, Ramesh Swaminathan, Arvind Bothra, and Vishal Rathi. It's my pleasure to welcome you all on our behalf. You already have the financial results in your hands, and you would have seen that we have had a good quarter. Sales for the quarter were flat YoY, while they were 4% lower sequentially, as India business, which is almost 34% of our business, is generally soft in Q4, while it was a very poor flu season in the US. But what's interesting and what you would have seen already, is that we have improved our EBITDA substantially by 500 basis points on YoY basis. On an annual basis, revenues are largely flat on YoY basis, down by 1.4%. As the entire year was ridden with COVID challenges across geographies, I think the team has done reasonably well to at least maintain the revenues. To me, what is very heartening to see, is that the EBITDA has definitely improved by about 220 basis points YoY for FY21, which we had promised you in the past and we do hope to keep working on this even as we go forward. With that little commentary, I would handover to Ramesh to share with you the financial details and then we'll open the floor for question and answers. Thank you very much and over to you, Ramesh.

Ramesh Swaminathan: Thank you, Dr Sharma. Dear friends, welcome to our results webinar. I trust all of you are keeping well and your family members are also doing well. It's a terrible time out there. It's important that we all stay safe. Let me walk you through the key aspects of our Q4 performance. Q4 has been a challenging quarter for us, given the surge in COVID cases with the second and third wave across many geographies, and this is true for a lot of other pharma companies also.

In this tough environment, the company's Q4 sales have come down by 4% sequentially and 0.8% YoY. The US business saw 4% growth sequentially, with the continued ramp up of albuterol. This is despite the continued impact of the weak flu season. Across various parts of the globe, a weak flu season impacted our sales both sequentially as well as over the previous year. However, in spite of the headwinds on the growth of the company, we continued on the path of improved profitability. The operating EBITDA, excluding the one-time settlement income in Q3, improved sequentially for the fifth quarter in a row due to the improvement in the business mix and



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sustained measures on the cost front. We endeavour to drive our sales and profitability by driving the profitability mix, bringing more niche products to our portfolio and continued improvement on our cost control and optimization initiatives.

Sales for Q4 were INR 3,759 crores compared to INR 3,917 crores in Q3, which is a 4% sequential decline and down by 0.8% YoY when compared to INR 3,791 crores in Q4 last year. Coming to geography-wise sales, US sales grew by 3.7% sequentially to USD 195 million in Q4 as compared to USD 188 million in Q3, and lower by 8% as compared to USD 212 million in Q4FY20. As you might recall, COVID was around the corner and there was a surge in demand in anticipation of lockdown conditions in America last year, and it was also a normal flu season last year. The sequential growth is driven by a ramp up in albuterol and other new products like posaconazole that more than offset the flu season decline QoQ. Demand for seasonal products continued to be weak on back of the weakest flu season in the last decade, leading to a USD 36 million fall in sales of oseltamivir, azithromycin and cephalosporins as compared to Q4FY20.

Coming to India business, Indian branded formulations saw a growth of 6.4% YoY in Q4 as demand picked up. As per IQVIA, Lupin's growth in Q4 was 5.9% vis-a-vis 8.5% for the IPM. Acute product sales have grown in Q4 versus de-growth that we had seen in Q1 and Q2 and is higher than Q3. For the full year, India branded formulations exhibited growth of 4.5% vis-a-vis the previous year. As per IQVIA, IPM growth is 4.3% compared to Lupin growth of 3.9%.

API sales showed a 25.6% decline QoQ with low volumes on some of our key antibiotic APIs on account of weaker flu season in most parts of the globe.

As far as EMEA and growth markets are concerned, EMEA grew by 14.6% QoQ due to strong demand in South Africa, NaMuscla and scale-up of Etanercept. Sales for growth markets is lower by 8.5% QoQ due to the second wave of COVID hitting us in several countries.

On the gross margins front, Q4FY21 gross margin was 65% as compared to 64.9% in Q3FY21. This is driven by improvement in business mix in US, led by albuterol. However, on account of slowdown in seasonal products for flu season, we have had higher write-offs in this quarter. Thus, the net improvement was just 10 basis points. Over the previous year, the margin improved by 210 basis points, which is primarily on account of better mix in US and higher API margin. This is partly offset by higher freight rates and high growth in low-margin business of Brazil and Australia.

We've done a stellar job when it comes to the employee benefit expense. In Q4FY21, this is INR 640 crores as compared to INR 707 crores in the previous quarter. If you recall, it was INR 764 crores in Q4 last year. Lower expenses in Q4 is largely due to one-time savings coming in from pruning up of annualized



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schemes and change in policy. We, however, expect employee costs to be in the sub 18% range in spite of the increments which will kick-in in Q1. We brought it down from 22.9% in Q1FY21, which is a very good achievement.

Manufacturing and other expenses in Q4 is at INR 1,118 crores as compared to INR 1,157 crore in Q3 and INR 1,152 crores in Q4FY20. The decrease of INR 34 crores YoY is driven by lower selling and promotional expenses, offset by higher royalties on partnered products.

On the EBITDA front, we have reported a fifth consecutive quarter of operating EBITDA margins improvement in spite of degrowth in sales. Operating EBITDA is 18.8% excluding forex and other income for this quarter, which is 20 basis points higher than normalized EBITDA of Q3. As you recall, in Q3, whilst the top line EBITDA margins were higher, it was because of one-time settlement income. You would also appreciate that there has been continuous increase over the last five quarters, which has been a result of several initiatives that we have taken on the cost front, including procurement, routes to synthesis, renegotiating contracts, rationalization of our sales force in America and other parts and so on. We continue to strive to work on this and we will see certain improvements coming across in the future as well.

We are particularly proud about our achievement on the Effective Tax Rate (ETR) front. In the course of the year, we have been working on various initiatives to optimize the overall ETR and it's reflecting in the full year ETR numbers. It's come down from 40% last year to 26.7% for the full year in FY21. In this quarter, it is particularly low because we had over-provided in the previous quarters and we've rolled it back. It is also because of the fact that several of our subsidiaries have turned profitable, especially America; further Brazil broke even last quarter. We expect the ETR to remain at similar levels in FY'22 and we will be continuously working to further optimize on this.

With this short introduction, I would open the floor for discussions.

Moderator:

Thank you. We will now begin question and answer session. Anyone who wishes to ask questions may raise your hand from 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 and your company name before asking a question. Thank you.

First question is from Damayanti Kerai. Please unmute yourself.

Damayanti Kerai:

Thanks a lot for the opportunity. My first question is on albuterol traction in the US. So, first, how much market share we have reached because Symphony data is, I think, not reflecting the pickup yet. And have you seen any change



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in market dynamics after recent entry of Sandoz in the market? Can you please comment on albuterol market?

Vinita Gupta: Yes, Damayanti. As per IQVIA reports, market share is just over 8% and it is kind of lagging. Obviously, our supplies are ramping up and our market share will continue to ramp up over the next few quarters. We haven't really seen any material change since the switchover to Sandoz, of the Proventil AG. So, really no shift in market dynamics. It continues to be a very strong opportunity for us, and we continue to ramp up our supplies as well as market share.

Damayanti Kerai: Okay. Vinita, ma'am, so pricing is largely stable in the market, right, for albuterol?

Vinita Gupta: Yes. So far pricing has been stable.

Damayanti Kerai: Okay. Good to hear that. And my second question is on the inhalers franchise. Can you update us on the status of gFostair launch in Europe? Earlier, you indicated to launch it by end of FY'21 and maybe you can comment on gBrovana opportunity. Should we consider this as CY'21 launch?

Vinita Gupta: gFostair, we made significant progress with the UK agency and are expecting approval soon. So, that should be launched soon thereafter in the next few months. gBrovana will be another material product for us for CY'21/FY'22. The inhalation portfolio, led by albuterol ramp up, followed by gFostair launch, gBrovana, gPerforomist will be a significant driver for FY'22.

Damayanti Kerai: Okay, ma'am. I have more questions. I'll get back in the queue.

Vinita Gupta: Okay.

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

Nithya B: Hi. This is Nithya from Bernstein Research. A related question again on your respiratory generics portfolio, if you can update us on what you might have heard from the FDA on your gSpiriva filing and again some color on when you expect to launch the product and how the litigation is progressing as well?

Vinita Gupta: Yes. We've had good communication with the agency. There has been a lot of back and forth over the last couple of months. We are in the process of responding to the agency's questions and feel pretty good about getting the approval for next year. The litigation is later this fiscal year. Again, we have said in the past, we feel pretty good about our position and our ability to launch the product next fiscal year.

Nithya B: Do you have a minor CRL? Once you respond, this is going to be a six-month review process, eight-month review process? Can you throw some color on that?



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- Vinita Gupta:** Yeah. We have got priority review on the product and would hope that by middle of next year, even with one additional round of questioning, we should get approved.
- Nithya B:** Got it. The second question was on tax rates. Ramesh, you were alluding to this, but just to get some clarity on what is your guidance on the tax rate that you expect next year? Is this likely to be in line with the fourth quarter?
- Ramesh Swaminathan:** Well, fourth quarter was really an aberration. You could take the full year as the guidance for the future as well. 27% - 28% is where I would place it.
- Nithya B:** Got it. I have a few more questions, but I'll get back in line. Thank you.
- Moderator:** Thank you. Next question is from Kunal Dhamesha.
- Kunal Dhamesha:** Hi. This is Kunal Dhamesha from Emkay Global. Sir, two questions. First on the employee expenses, you said there was some one-off, but I missed that comment. What was the quantum of that one-off? And if you can share that, that would be great.
- Ramesh Swaminathan:** I said the one-off is essentially because of the fact that we had provided for sales incentives and the like, which didn't materialize because the actual sales were lower. So, we wrote it back. You could expect an increase in the quarters to come. But we're still keeping the overall costs on a leash. It's going to be in the 18% range.
- Kunal Dhamesha:** Sure. And the second question is on the status of various plants that are currently under regulatory issues? Any update on that front? Are we seeing any progress in terms of the desktop audits in any of our plants?
- Nilesh Gupta:** Kunal, as you know, the FDA has come up with a remote interactive evaluations guidance. In the best of our understanding, that has not really kicked in meaningfully for any plant in India yet. So, the status remains the same. We have told the FDA that we are ready for our Goa, Pithampur Unit-2 and Tarapur plants. We are hoping that this is going to be the way to engage with the FDA because, right now, it's extremely unpredictable of when the FDA would be able to travel to India. We believe that this will be the way. I think it's a big positive that they've come up with this guidance and it really is applicable for everything. It is for surveillance, it's for OAI's where CAPAs are complete and PAIs as well. Most other agencies have adopted this approach already and we're hoping that the FDA will start reflecting it in their actions soon as well. We don't have a specific update at this point of time, but the fact that the FDA has come up with that guidance and approach is a big positive.
- Kunal Dhamesha:** Sure. Thank you. Thank you, Nilesh.



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- Moderator:** Thank you. Next question is from Neha Manpuria.
- Neha Manpuria:** Thank you for taking my question. This is Neha from J.P. Morgan. Vinita, on the US business, while you know albuterol, like you indicated, could see a ramp up, just wanting to understand what led to supplies being shorter than expected. Because in Feb, we had indicated to the product gaining traction over the next few months, which hasn't really happened. What's really happened and what gives us the confidence that this would improve going forward?
- Vinita Gupta:** There were supply issues, especially coming out of the valve supply in the UK, just given the impact of the second wave. But we did have a ramp up of supply, Neha, and that continues. We have a strong commitment now on supplies. We did ramp up albuterol QoQ. It doesn't show up in share as of yet, because share will lag the market supplies, but it will show up as we get additional new data from IQVIA. Now that we have visibility on supply of valves -- of course, everything is COVID permitting, our team is working very hard with the valve supplier to ensure that we get what we need. We feel pretty good about that.
- Neha Manpuria:** And we are still committed to the 20% fair market share that we had indicated in the past.
- Vinita Gupta:** That's right. It's not going to be overnight, of course. We are building it up in a very prudent manner. We are looking to maximize the opportunity and expect to achieve it by the end of FY'22.
- Neha Manpuria:** Yes. And my second question, just extending it on the US business, giving one of our key products could likely see erosion in the first quarter, we have obviously albuterol, but if you could give me a little bit of sense on how you see your US business shaping up for FY'22 in terms of what you expect in new product launches? What would be the key products that could drive the growth in this business?
- Vinita Gupta:** The largest part of the growth is the inhalation portfolio for FY'22, starting with albuterol and then gBrovana, gPerforomist, all contributing towards growth in FY'22. In the near term, early in the fiscal year, we have the challenge with additional competition on famotidine, which has been built into a material product for the organization but are managing within that competitive landscape to hold on to significant share. We built a lot of goodwill with the customers, over time, as we ramped up the product with the ranitidine decline. We feel pretty good about holding on to significant share and maximizing as much value as we can. There obviously is going to be erosion on the famotidine front, but we expect to more than make that up and support a very strong double-digit growth with what we have planned around albuterol, the other inhalation products, gBrovana, gPerforomist and also growth in our in-line products. This past year, we had challenges from a supply perspective, COVID-related on the in-line products. We expect to really



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get back to normalized levels in FY'22, which will also help the double-digit growth.

Neha Manpuria: Understood. Thank you so much.

Moderator: Thank you. Next question is from Rohit Jain.

Rohit Jain: Hi. My name is Rohit. I'm calling from Tara Capital Partners. I just had one high level question. I just wanted to understand the promoter's commitment to the business. What I want to ask is, are we committed over the medium to longer term or are we a willing seller at the right price? Thank you. The context of this question is that a lot of things keep coming up in the market. So, just wanted to get some clarity over there.

Vinita Gupta: Well, let us put that to rest. We are extremely committed to the business. To us, this is not just a business, it's our family's legacy and we take a lot of pride in what we have built. I believe that we've had a couple of challenging years, which may have led to this kind of rumor, but we are in a very strong position today. We've really turned around our business, have very significant growth drivers when we look at the next five years, and our complex generic strategy, our specialty strategy, our biosimilar strategy, India market growth prospects, our US market growth prospects, other regions. We are very excited about the business and we'll continue this legacy.

Rohit Jain: Okay, thanks. That's a very clear answer. Really appreciate it. Thanks.

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

Prakash Agarwal: Yeah, good evening. Thanks for the opportunity. Just you know, some clarification here. Obviously, double-digit growth with an exit rate of USD 195 million is done deal, right? So, you were, USD 800 million last year, and FY'21 you ended with USD 720 million for US. So, 10% is USD 800 million and you are already doing USD 195 million. So, I totally understand, last year, COVID year and there was a mention of cephalosporin business, azithromycin and all our antibiotic business had a hit due to COVID also. Looking forward, with so much in the pipe which we just talked about, is there a broad level number we can work with for FY'22 and FY'23 in the US?

Vinita Gupta: Prakash, we don't like to guide and we're still dealing with the impact of the pandemic. In India, in particular, from a supply perspective. As much as the team has worked very hard to ensure that we continue, challenges do crop up. We remain very confident of growing it. Our goal really, in the next couple of years, is to get to that billion-dollar plus sooner rather than later, but we know that we need to really get through a couple of quarters and just execute and deliver to make that happen. We certainly think that in the next two years, we are set to cross the billion-dollar mark.



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- Prakash Agarwal:** Okay. And tying this with the margins, and obviously, there was a comment that US has just turned EBITDA positive, so with this adding about -- over USD 200 million over next two, three years, so any color you want to give in terms of margin expansion or reiterate what we have said in the past?
- Vinita Gupta:** What Ramesh was mentioning about EBITDA positive was more for the US entity from a tax perspective, which has led to that optimization of the tax from 40% the year before to 26%-27% this year. The US has always been EBITDA positive. It has been a very strong EBITDA contributor in FY'21 and will continue to be a bigger contributor in FY'22 and beyond.
- Ramesh Swaminathan:** Prakash, I mentioned Brazil as becoming EBITDA breakeven. America has always been profitable. We took an impairment in the last couple of years and that's where we actually had a lot of NOL, so you're not paying taxes in America. That's what we meant.
- Prakash Agarwal:** Yeah, fair enough. But any reiteration on the margin expansion which we have said in the past for the next one to two years?
- Vinita Gupta:** Yes, we definitely expect margins to continue to expand. This past year, we've had a significant QoQ improvement over the last five quarters from the 15% level to the 18.8% level. We expect to be 19% plus in the next fiscal year. Certainly, in FY'23, we are working hard to get to that 21% - 22% level.
- Prakash Agarwal:** That is very helpful. And last question on the India business. I mean, there is a comment on the AIOCD -- the industry body talks about monthly data points, that the use of medicine is to increase given the new surge of direct and indirect COVID-related products and the aftereffects, be it the steroids and leading to more diabetes, cardio, any sense there? Do you expect this overall use of drugs and the volume to increase what you've seen in the last year?
- Nilesh Gupta:** In the near term, this is reflected much more in anti-infectives and everything that goes into COVID care. It's a pretty wide spectrum, right from products like budesonide to a product like baricitinib, Fabiflu and the like. That's what we're seeing right now, but what is getting highlighted very clearly is that India is terribly under-indexed on the healthcare front, and there has to be investment. There certainly is heightened sensitivity around that. I think it's a real crisis, which is going on in India right now. Obviously, we're seeing a very grim situation. But I think it's hard to predict at this point of time, but everything seems to indicate that there will be heightened focus on healthcare going forward and that will lead to further market expansion.
- Prakash Agarwal:** Thank you. All the best.
- Moderator:** Thank you. Next question is from Surya Patra.



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Surya Patra: Yeah, thanks for this opportunity, sir. First question, if you can let me understand, what are the kind of offers that you are currently seeing levothyroxine and the relaunched metformin in the US currently.

Vinita Gupta: On levothyroxine, quarter by quarter, we have grown share. At the start of the fiscal year, we were at the 12% market share level within the generic market. Today, we're at 18.7% level. So, have seen a ramp up quarter after quarter in levothyroxine. Our team worked hard to deliver that, and we'll continue on that path to build share on a profitable basis.

On metformin, we had to unfortunately get out of both gGlumetza as well as gFortamet due to the NDMA concern. We're very pleased that, within a quarter, our team got the product back to market. It was at lightning speed that our team worked to make that happen. But as we got back into the market, we had to really earn our share again. Very pleased to say that we are already at 50% plus share in gGlumetza again. Of course, like I said, we had to earn our way. So, the pricing is at a different level, but it continues to be an important product in our portfolio. gFortamet, we are yet to launch. We are in the process of planning the launch of gFortamet, but we expect to launch that back again.

Surya Patra: Industry-wise market that one can consider or target from that, if you can just provide.

Vinita Gupta: I guess I would just say that gGlumetza at one point in time was a very important product in our portfolio and now it's a smaller product. Even in FY'20, it was a smaller product and it's become even smaller.

Surya Patra: My second question is on R&D, ma'am. R&D and, obviously, have an indication on margins. So, if I see the R&D performance of Lupin for the last five-year period, let's say, what is the cumulative R&D, both revenue as well as capital R&D spend of the company, and comparatively see with the incremental revenue growth or business growth it has provided? Then the trend may not be great, possibly because the kind of front-ending of R&D spends on the complex projects without any commensurate sales from those. But I think the kind of visibility that is there, at least five inhalation products over next two years, I would say, rather, which can possibly bring in a significant J-curve kind of a recovery on the business front and similar kind of implication on the margins, driven by sales progress. But, simultaneously, I think, which is difficult for us to estimate is that the moderation in the R&D spend, what we can see, so that can really surprise on the margin front. So, if you can deal with these two aspects, then what expansion that the specialty projects that you will be seeing from the possible four key product opportunity over next two years and what kind of a further boost on the margin side that you can achieve because of the moderation in the R&D spend?



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Vinita Gupta:

You have multiple questions there. But I'd say that your point was correct that the investment was front-loaded on the complex generics on all our platforms, whether it is inhalation, complex injectables, biosimilars. It took time to establish them. It took time to establish capabilities. It took time to really get the pipeline together, but we are starting to see the results of it. As we look now, at the inhalation portfolio paying off. We will see in the next couple of years, the ramp up of the inhalation portfolio business. Then the injectables will start contributing. We now have a very solid portfolio on the injectables front, with depot injectables, peptides, iron products and liposomal products through a partnership. So, that will start contributing in the next two to three years. Biosimilars started contributing ex-US with Etanercept. In the next couple of years, we would start seeing contribution of products like Pegfilgrastim and then Ranibizumab and beyond. As we look at return over the next five years, the complex generics are our biggest growth drivers when we look at our five-year plan – revenues and also margins. Overall, your question on R&D investment, as Ramesh said at the beginning of the call, that we have managed to keep our R&D investment under control. We were over 10% two years ago. We were at the 9% level in this past year. It will continue to decline as a percentage of sales, while our R&D investment continues to increase YoY, just given our revenue potential is also pretty strong now going forward. I hope that answers your question.

Surya Patra:

Yes, ma'am, to some extent. But is it fair to believe that the margin expansion trajectory could be really strong over three year or kind of, but it would be, to a greater extent, back-ended kind of a trend? Or in the interim period, it could be a staggered one? Is the kind of indication that we are talking about?

Ramesh Swaminathan: We expect to get to the 22% range as the base. Whenever there is the introduction of a new product, it could spike up to 26%, 27%, but come back to the same level. That's going to be our endeavor. As Vinita and others were also saying, it's essentially going to be on the back of three things, essentially the kind of products that we would be bringing to the market. Vinita did give us a flavor of the fact that we are looking at a host of complex injectables, inhalation products, biosimilars, and of course, specialty itself at some point. Apart from that, we have been continuously working on cost improvement in terms of procurement policies, in terms of routes to synthesis, re-negotiating on contracts, looking at rationalization of our workforce on the sales front, on the R&D front and also the manufacturing front. All of this has been paying results. Obviously, there is more to come. It's a continuous exercise. With these, we do believe that we've been marching in the right direction in the last four to five quarters. There is more to be done. During this year, between 19% to 20% would potentially be the target for FY'22 and improvement on that in the next couple of years.

Moderator:

Okay. Thank you, Mr. Surya. Next question is from Mr. Saravanan Viswanathan.



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- S. Viswanathan:** Etanercept, what is the update? How has the launch in Germany and Belgium played out? France markets and other markets, your target markets, have the launches taken place?
- Vinita Gupta:** It is launched in the last six months, in Germany, Austria, Eastern European markets. France is yet to happen, but it's in the works. Germany was the highest priority market as we were building supplies for the partnership with Mylan and we work to maximize that. We have seen a ramp up in revenues quarter-after-quarter between Q3 and Q4 on Etanercept and we'll continue to expect that. Going forward, look to launch in other markets, both in Europe as well as ex-Europe, Australia and other countries.
- S. Viswanathan:** Okay. And Pegfilgrastim, is the go-to-market timelines, is it happening this year?
- Vinita Gupta:** Well, the go-to-market plans, yes. But we just filed the product, and are still waiting for acceptance from the agency. That facility has not been inspected by the FDA. We're going to have to see what the timeline looks like from an FDA inspection standpoint. Will they accept a remote inspection or will want to really wait for onsite inspection? Really, the inspection will be the determining factor on the launch date, but we're getting prepared to be in a position to launch within 15 to 18 months.
- S. Viswanathan:** As regards the India business, would we expect to grow in line with the market for this year?
- Nilesh Gupta:** I think we should be back to double-digit growth. Obviously, the current quarter, we are seeing growth, but more connected with products for treatment of COVID. Otherwise, the market had started to bounce back, doctors had come back. Now, doctors have scaled back a little bit from clinics. Patient footfalls have come down a little bit as well. But we expect double-digit growth in FY'22 out of India.
- S. Viswanathan:** Thank you. And last question is on the debt levels. So, can we expect it to go further down? Or do you have any inorganic plans?
- Ramesh Swaminathan:** We are a near debt free company. We have actually repaid our Gavis loan during the course of this quarter itself. We have plans and looking at acquisitions. We would raise up when the occasion really demands it. That I think, would be good for the shareholders also.
- S. Viswanathan:** Okay. Thanks a lot.
- Moderator:** Thank you. Next question is from Mr. Sameer Baisiwala.



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- Sameer Baisiwala:** Hi. Greetings, everyone. And thanks for taking me in. Quick question on gRevlimid. Vinita, how are you thinking of monetizing this asset? Can this be a 2022 calendar event like four, five other companies?
- Vinita Gupta:** Yes, Sameer. We are looking to see how we can bring it in sooner rather than later.
- Sameer Baisiwala:** Okay. Excellent. And second question is on gSpiriva. Vinita, just in terms of court process, where exactly are we in terms of discovery, Markman's hearing and what's your best guess - when could there be full-fledged trial that can start?
- Vinita Gupta:** I believe, right now, it's running slow, but will pick up pace in September, Sameer. So, September onwards based on the court proceedings, we'll get a read on the litigation timeline.
- Sameer Baisiwala:** Vinita, going by the other examples, so many that happens, the patent challenge, it looks like where your case is right now, it is almost impossible that you will get a district court ruling by middle of 2022?
- Vinita Gupta:** In the last COVID year, we have seen that courts have been very efficient on remote proceedings. We'll see what happens, but it has been slow, the litigation timetable. So, yeah, it could take a little bit longer. We still expect the product to be launched in FY'23.
- Sameer Baisiwala:** Okay. That's very nice. And one final question is on -- I don't know how you'll respond, but on USFDA. I'm sure the agency must be having a massive amount of backlog of both routine inspections, site inspection, product specific inspection, and then all the OAI, warning letters, etc. So, as and when things open up, what do you think would FDA prioritize, whether it's virtual or physical, and what would it mean for companies like yours which has multiple manufacturing sites? Can there be a bunching of big issues? Will it be bad news or good news? Just your thoughts on this.
- Nilesh Gupta:** Maybe I can start and, Vinita, you could add. First of all, I think FDA is very cognizant of the backlog that is getting created of surveillance. In addition to the surveillance inspections, just all the other inspections which are for-calls. From our perspective, we had a great start last year up to March where we had six consecutive positive outcomes out of FDA inspections. They cited some of the observations which have plagued us for a while, like investigations as well, and yet we received the EIRs and satisfactory closures. We've worked a lot, especially on some of the India sites, like Pithampur Unit-2, lesser so in Goa and Tarapur because there wasn't a deeper fix that we wanted to put in place. We would welcome the flow of inspections to restart. As you know, I think we're over-indexed on the number of sites which are at some degree of non-satisfactory compliance. It is a clear organization goal that we have to overcome those.



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- Vinita Gupta:** Just to add to that. I think the priority would be first to market products, first to files, high priority products, especially those that have surged through COVID will continue to be a priority.
- Sameer Baisiwala:** Okay, thanks.
- Moderator:** Thank you. Next question is from Mr. Kunal Randeria.
- Kunal Randeria:** Yes, thank you. So, my first question is on the US business. I believe you have launched close to 15 products in the US this year. But if I go through the press releases, I see that the number of products in the market currently has gone down from 175 to 168 or so. Does this mean you have discounted around 20, 22 products? Is my understanding correct over here? And if so, is the portfolio rationalization exercise complete or you're still looking to rationalize some of the non-profitable SKUs this year?
- Vinita Gupta:** In the last couple of years, as we optimized our business, we definitely looked at portfolio optimization where it didn't make sense. We got out of the product. Overall, the portfolio rationalization is behind us. We think that pricing, the kind of challenges that we faced, until year before last, we think, are behind us. That's not to say that price will not continue to be a challenge, in the generic business that continues to be a challenge. But we hope that the single-digit price erosion that we contend with, we can offset it with volume growth, continuous cost reduction efforts. We do think that the portfolio rationalization process is behind us.
- Kunal Randeria:** And it would be fair to understand that this is what led to your gross margin improvement in the current year.
- Vinita Gupta:** The gross margin improvement was definitely product mix, good part of it led by Albuterol as well. High margin products that we grew.
- Kunal Randeria:** Sure. Okay. My second question is on the India business. I was just wondering, you know while Nilesh did mention we are going to see double-digit growth, any particular area or any particular therapy just doing particularly well for you and any therapy where you are sort of lacking, going behind the market? I think especially on the acute side. So, what's the strategy to revive these? Just a bit of a more understanding on how you're looking at the India business.
- Nilesh Gupta:** As you know, the big three areas for us in India are cardiac, respiratory and diabetes. In particular, diabetes is the fastest growing amongst the segments, ~20% at this point of time on a significant base. Again, as I've said in the past, we are not number one in any of these. I think we're number three in pretty much all three of them, and there is significant room for growth. All these three will continue to be the big areas for us to grow. Obviously, we are weighted more towards the chronic side than the acute. Right now, we're



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seeing a resurgence on the acute, which is going to help pick up sales as well. But that's not the biggest strategic story. I think the biggest strategic story remains around these three areas and then carefully adding others. We are highly under indexed in areas like dermatology, for example, and even weaker in areas like women's health or even in vitamins, minerals, and supplements. We're in everything, but the idea is to really build bigger brands and build deeper positions in select areas. These couple of areas like dermatology, VMS are the areas where we would want to build. But the main focus will remain on these three.

Kunal Randeria: Got it. Thank you, and all the best.

Moderator: Thank you. Next question is from Mr. Ranvir Singh.

Ranvir Singh: Sir, my question pertains to API business. So, after witnessing three quarters of very good number, we see a blip in Q4. So, what would be the run rate we should take on that API side?

Nilesh Gupta: The API business going down in Q4 is really a sign of the flu, the anti-infective business, how it's been impacted globally. Big products like cefalexin and the like are significantly down globally. We talked about the US, pretty might having a nonexistent flu season this past year. The same has been the story in other markets as well. That has been the main reason for driving this. We do believe that it will start picking up. We already see signs of it picking up in important markets like China for us. Likely Q2 onwards, we would see it picking up again. There is a significant bunch of new products that we have planned on the API business as well. We've been lagging on building enough new big API products, and that is a focus area at this point of time.

Ranvir Singh: Okay. So, just wanted to understand from industry perspective also, the last three quarters for industry itself, that API business has been very strong. So, wanted to understand whether the competition or pricing scenario is getting changed versus last few quarters. That perspective wanted to understand.

Nilesh Gupta: Not really. We are all facing input cost increases from markets like China, for example, and that's pretty much across the API industry. I don't think there is a fundamental change in the competitive dynamics, which is driving this. This is primarily demand related.

Ranvir Singh: Okay. And another related to that, that API business, normally, we get higher than the company's margin, average margin or it is lower than the average margin on EBITDA front?

Nilesh Gupta: Typically, at the gross margin level, obviously, finished product business would be of higher value. The API business is almost at a similar EBITDA margin at the company.



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Ranvir Singh: Okay. That's it from my side. Thank you.

Moderator: Thank you. Next question is from Cyndrella Carvalho.

Cyndrella Carvalho: Hi. Thanks for taking my question. I want to understand, over the past two years, the margin contraction that we have seen, if you can highlight what was our learning from? And if we could highlight which were the regions which were actually creating this kind of impact and what is the strategy going ahead to commit to the 22% level that we just said on the call?

Ramesh Swaminathan: No, essentially, as you'd recognize, it's really a function of our sales growth and cost. If costs grow at a faster pace than sales and you potentially have an EBITDA margin problem. The last couple of years, our sales were stagnant, whilst the expenses grew. Particularly so, for example, you saw manpower costs going up significantly, ramping up quite significantly. In the first quarter, it was close to about 22%. As long as we are able to bring in newer products and keep an eye on cost, we should be okay, and that's exactly what we have been trying to do for the last now several quarters. We have been working on several projects, on all the cost lines, starting from gross margins viz. procurement costs as well as cost of conversion. There's a lot of focus on that. We worked with external consultants to get that focus. When it comes to cost lines beyond that, for example, the indirect cost, SG&A expenses, contracts that we pre-negotiated with a host of our vendors, we have brought in productivity gains on R&D as well as the sales force. We have rationalized sales force in various parts, all this helped to rein in the costs. During the course of the year, we brought down the overall manpower cost, and it's something that we alluded to even during the course of this call. We spoke about the fact that it came down. In this quarter, it's been particularly low. All of this helps. The introduction of products across various markets, across the most important markets, would certainly help moving, nudging the EBITDA margins upward going forward. And of course, there is always going to be a continuous emphasis on cost reduction

Cyndrella Carvalho: And regionally, if you have to highlight any particular region?

Ramesh Swaminathan: Among the most important regions for us, America remains the most dominant region and there is, of course India; we have never taken the eye off the ball when it comes to India. There is operating leverage in India, which we wanted to optimize on, obtain leverage in other parts, including Europe, APAC region and of course the Latin American region. I wouldn't like to actually place emphasis on one particular region as being the cause for decline. It's singularly because of the fact that we have not had enough products going for us in America.

Cyndrella Carvalho: Okay. Of course, we understand India and US are the key regions. I just wanted to understand if there was any other region which was creating any



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impact, particularly, or else it is the product launches that we have seen through it.

Ramesh Swaminathan: We also had specialty losses in America because Solosec didn't get the levels that we expected it to. That contributed to losses in America. We have rationalized the sales force in order to keep that on a leash.

Cyndrella Carvalho: Okay. And just to Vinita. Vinita, could you highlight our strategy on Solosec going ahead? And any other new product additions, especially on the specialty side in US that you would expect over coming two to three years?

Vinita Gupta: Our strategy through the pandemic was to really conserve cost and restructure. We have brought spend down significantly through a combination of reduced footprint of the sales force, plus virtual interaction with the physicians. At this point in time, we are focused on the next major lever, which is the trichomoniasis launch, which we hope to do in the next quarter actually. We are waiting for feedback from the agency and we'll time really a re-launch of the product, with lower level of spend at this point in time. That's where we are on Solosec. With the changes that we have made, we expected some disruption. We have seen disruption. But in the last couple of months, we have started to see some growth, although minor. I think the major trigger for us is going to be trich and likely see the impact in the second half of the fiscal year. Simultaneously, we look further for opportunities. We are looking at a couple of other opportunities right now that potentially will be accretive for the women's health business and building up the pipeline. We have had really good success, the three programs in the pipeline on the women's health front with the agency. In particular, there are two programs where we've had success with the agency and progressing them into the clinic very rapidly.

Moderator: Next question is from Forum Parekh.

Forum Parekh: Yeah. So, I had two bookkeeping questions. I see the raw material expenses as a percentage to sales have come down. And this is the second quarter where we have recorded lower percentage to sales. So, just wanted to know like what the reason is and is it sustainable. And second question is on the Capex front. Do we intend to have any incremental Capex in the next two years?

Ramesh Swaminathan: Firstly, on the raw materials front, as I was just alluding to a few minutes ago, we have been working on bringing down the overall procurement cost and the like. Some of it is because of that, the outcomes of those initiatives. And, of course, there's always the sales mix and the production mix, which goes into the financials for any particular quarter. It's actually really a resultant of that.



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The second was on capital expenditure. We really are into an optimization mode on everything, given the idle time. This year, we would think that it's going to be close to the INR 1,000 crores.

Forum Parekh: Okay, that's helpful. Thank you.

Moderator: Thank you. The next question is from Harsh Beria.

Harsh Beria: Hi. I have a question on working capital of the business. So, this has structurally increased from, let's say, 100 days level to like 150 days, 160 days. What is the sustainable working capital levels that you guys see going forward?

Ramesh Swaminathan: There has been an absolute decline vis-a-vis the previous quarter. But we take your point that it's gone up over the last couple of years. Even now, it's hovering around the 145 operating days and we are trying to work on that. It's a function of, when do we make those sales. As long as it is something that is within due dates, it doesn't get translated into cash. And that's the reason why you find that the overall accounts receivable, for example, is on the higher side.

Harsh Beria: Yeah. This year, I think the receivables actually did a little better. I think it was inventory which contributed to higher working capital. I was wondering, can this come back to 100 days, 120 days in the next few years?

Ramesh Swaminathan: We endeavor. We have been trying to work on all of that. But as I said, with COVID, there have been some supply chain disruptions and so on. It really pays to stock up. It has been a function of the context in which we are operating as well.

Harsh Beria: Yes. That's it, thanks.

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

Dr Kamal Sharma: Thank you. This brings us to the close of today's session. Hope you got the clarity that you were seeking. Look forward to connecting with you all next quarter. And I'd like to thank you on behalf of my team for your continued interests in our company. And in the meantime, look after yourself, take care, be safe and be healthy. Good luck. Thank you.

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