



August 26, 2021

**BSE Limited**

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

✓ **National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**Mumbai - 400 051.**

**Dear Sir/Madam,**

**Transcript of Q1 FY2022 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 Q1 FY2022 Earnings Conference Call held on Wednesday, August 11, 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 Q1 FY2022 Earnings Conference Call”

**August 11, 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. VISHAL RATHI – VICE PRESIDENT, CORPORATE FINANCE, LUPIN LIMITED**
- **MR. GAURAV TINANI – SENIOR MANAGER, INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**

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**Moderator:** Hello everyone. Welcome to Lupin Limited Q1 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 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 friends. This is Kamal Sharma. I welcome you all to this earnings call. The present quarter has been kind of a mixed quarter for us. On one hand we were very happy to receive research income of US\$50 million, on the other we had a few unanticipated events on the operating side. For the coming quarters, the prospects of business remain promising, especially going by the ramp-up that we're seeing in complex generics currently, and the growth of the India business which has been very promising for us.

With that, we do feel that in the coming quarters, we would have a much more promising performance to discuss with all of you. To give you the details of various parameters, I will hand it over to our CFO, Mr. Ramesh Swaminathan. Thank you.

**Ramesh Swaminathan:** Thank you Dr. Sharma and Good evening friends. I trust that you and your families are keeping safe. In a quarter that was impacted by pressures in the US, we are pleased to deliver 22.2% growth YoY and 12.7% growth QoQ, bolstered by US\$50 million milestone received from Boehringer Ingelheim in this quarter. Business without the milestone income grew by 11.4% YoY and 2.8% QoQ.

QoQ growth was driven by our India business that grew 27.2% and Growth Markets that recorded 9.7% growth. Indian market grew 39.2% including COVID therapies and 32.4% excluding these. The acute market grew 52.5% and we grew 45.4%. The chronic market grew 19.4% and we grew 22.6%. HCP attendance is back to 90% levels and patient footfall is 77%. Our call average is 9.6. We see high-teens growth in India for the year overall.

US revenues were down sequentially due to competitive pressures on some of our base business products, famotidine in particular, as new competition entered. Additionally, there is an element of failure to supply due to supply chain issues that cropped up last year and that we have settled with our customers currently. Further, for our Albuterol generic, we're transitioning from spot buying to long-term contracts. Albuterol is ramping up nicely and based on our commitments, it is on track to get to 18% - 20% market share with a major pickup in Q3. Brovana AG has been a successful launch in the quarter and we expect it to contribute to growth in the current year. We

remain committed to grow our US business, both with our in-line products as well as ramp-up of Albuterol and Brovana AG, continue above market growth in India and of course ensure growth in every part of the business. We feel extremely good about our NCE efforts and we are exploring ways to better fund the path forward, including a potential spin out.

Coming to margins, gross margin as a percentage is down to 63.9% due to change in reporting of partnered products in the US. Royalties on partnered products were reflected in the SG&A, manufacturing and other expense line earlier and is now reflected in the gross margins line itself. On a net basis partnered products are EBITDA accretive. Gross margin was also impacted by change in sales mix, so far as India vis-a-vis America is concerned. US margins were lower this quarter, driven by increased competition and slower ramp-up of Albuterol.

Whilst the quarter's profits were bolstered by Boehringer Ingelheim MEK program income, despite a tough operating environment, we see substantial room for growth. Employee cost was up vis-a-vis our Q4, primarily due to increments in India and higher sales incentives for IRF given the significantly higher sales in this quarter. Q4 last year was also significantly lower given certain incentive reversals in India. Amongst our peer set, we're the only ones that were able to bring down the manpower cost down as an absolute number in FY '21. We intend to maintain tight control on this line, while ensuring growth for the future. Manufacturing and other expenses were down 8% QoQ. This was partly because of the reclassification of partnered products royalty into COGM, as I spoke before. Promotion expenses went up because of increased business, especially in India. R&D expenses were 9.7% of sales and we expect to hold this number tightly without losing out on opportunities. EBITDA without NCE income and forex loss stood at 14.3%, a level that we are not happy with at all, after the EBITDA improvement that we delivered through the quarters last year.

We see meaningful uplift in the second half and remain focused on journey of expanding margins, by driving strong double-digit revenue growth and optimizing on cost, whilst ensuring the safety of our people and the highest standards of compliance. While we see our business in particular in the US, improve quarter after quarter based on Albuterol and Brovana AG ramp up and stabilizing base business, we have embarked on accelerating additional optimization efforts across our manufacturing and supply chain, including tackling idle cost for product categories where the demand has dropped. We are looking at finding solutions for areas like specialty, biosimilars and NCE, including spinouts.

Whilst we are not happy with our performance, we remain committed to improve our business throughout this fiscal. We expect revenues to grow in the double-digits, both in India and in other parts, including America and EBITDA to be 17% to 18% in the second half, which is lower than our earlier

guidance of 19% to 20%. We see meaningful bounce back in the second half, driven by increased sales in Albuterol, higher base in India and growth across various markets.

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

**Moderator:** Thank you. We will now begin 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:** Thank you for taking my question. First question on the EBITDA margin guidance that we have given. I think I probably misheard its 17% to 18% in the second half or it's for overall FY '22?

**Ramesh Swaminathan:** We believe that the second quarter would also be a tough quarter for us. We expect the EBITDA margins to kind of ramp up in the second half, so we are saying about 17% to 18% is what we'd be reaching in the second half of the year.

**Kunal Dhamesha:** Overall, then FY '22 would be somewhere around 16% - 17% and that would exclude the US\$50 million income, right?

**Ramesh Swaminathan:** Yes, that is correct.

**Kunal Dhamesha:** Sure, thanks for the clarification. In terms of the Albuterol when we say that we continue to hold our target for 18% to 20% market share, is that the market share of the entire Albuterol market or it's part of the generic Albuterol market?

**Vinita Gupta:** Its share of the entire Albuterol market.

**Kunal Dhamesha:** And where would we be currently?

**Vinita Gupta:** Right now, based on the weekly between 12% to 13%.

**Kunal Dhamesha:** Okay. When you say that there was some settlement related to the failure to supply. Where that settlement has been recorded? In which line items in P&L?

**Ramesh Swaminathan:** It's been netted off from the sales itself.

**Kunal Dhamesha:** So, you would have supplied some quantity, for which you would not have received someone money -- something like that.



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- Ramesh Swaminathan:** It's something like actually saying that there'll be a penalty paid for our inability to supply in the past. So, to that extent it's netted off.
- Kunal Dhamesha:** Sure. Yeah and lastly if I can squeeze. In terms of specialty in the US - Solosec, what would be our current investment from P&L after the rationalization of the cost?
- Vinita Gupta:** Roughly US\$20 million, in terms of EBITDA burn.
- Kunal Dhamesha:** Okay. Thank you.
- Moderator:** Thank you. Next question is from Mr. Prakash Agarwal.
- Prakash Agarwal:** Hi, Good evening. Couple of questions. One is what I hear or what I understand the signal right is Albuterol scale up from Q3. I understand in Q4, you had mentioned that what the understanding was that you got some stock filling done in all and there is some normalization in Q1, but why signaling Q3 and not Q2?
- Vinita Gupta:** Prakash, we strategically moved from one-time buys because of our limited supply through Q4, into more longer-term contracts. It's just the phasing of those contracts. Customers already had stock and they are phasing in our products. It's already started based on that 18% to 20% contracted business, but it's a buildup.
- Prakash Agarwal:** Would the pricing be any different versus a short-term versus long-term contracts?
- Vinita Gupta:** The long-term contracts are higher volume, a little bit lower pricing, but still very profitable, very high margin.
- Prakash Agarwal:** Okay. Understand that and do you think this opportunity remains four players, five players kind of market and you don't expect anything in the near to medium term like calendar '23. '22 is where we see more competition coming up. Is that a possibility?
- Vinita Gupta:** We are not seeing any additional competition coming up. We haven't heard anything new from Perrigo on their ability to get back in, tracking it very closely. So, nothing in the next 12 months to 18 months that we can see.
- Prakash Agarwal:** Got it. And secondly on USFDA issues around. We are hearing some companies seeing audits. Are we somewhere near to that and is our CAPA plan fully done for the three plants or now four? If you could update that, please.
- Nilesh Gupta:** I can take that. Prakash, as you know we've told FDA that we're ready for our Goa, Pithampur Unit II and Tarapur sites. The status really remains the same.

We don't have visibility at this point of time. We are aware that a few audits have started now. We believe they are mostly being conducted by the FDA-India office. We've had remote interactions more for regular surveillance kind of inputs. But right now, no particular traction on these three sites. Obviously, our goal is to remain in a state of readiness for imminent inspection at any point of time in these three sites.

**Prakash Agarwal:** Okay. And a quick one, if I may on Brovana. Why AG? We had a filing, so what's the background here?

**Vinita Gupta:** We were able to really get the authorized generic that allowed us to get into the market much earlier and before any of the other competitors. It's proven to be a very successful launch.

**Prakash Agarwal:** No but I mean, I understand gross margins and EBITDA margins are in the range of 15% to 20% for AG, whereas we could have a long tail. So, the cash flows you're seeing is much superior in AG? I mean what's the logic here.

**Vinita Gupta:** Both cash flow as well as margins. Margins are EBITDA accretive with our AG.

**Prakash Agarwal:** Okay, thank you. All the best.

**Moderator:** Thank you. Next question is from Mr. Saion Mukherjee.

**Saion Mukherjee:** On the US, the decline that you have seen QoQ, you mentioned three- four reasons for that. Can you just help us understand, like how much each one of them contributed to this sequential fall of US \$20- \$25 million that we have seen?

**Vinita Gupta:** We're not going to quantify by product, but I would say top down - it is Albuterol, FTS, Famotidine and couple of other baseline products also like Metformin and Levothyroxine that saw pricing pressure because of additional competition.

**Saion Mukherjee:** Okay. And Vinita just this on pricing pressure. So, we are kind of hearing multiple things from multiple companies, what is your take on this. Why are we seeing this sudden increase in sort of it feels like there is a surge in pricing pressure? I mean we are at a time when you know, you will see lot of inflationary pressures in general- freight costs are high. What is the economics working out in your base business and what is your take on what's happening in the marketplace as far as general pricing environment is concerned?

**Vinita Gupta:** The pricing environment has been tough, especially in the last couple of months. One major event was Econdisc broke out of the WBAD consortium to independently run their GPO and open their whole portfolio to a bid. So that really got companies aggressive from a pricing standpoint. Second, because of the FDA slowdown of inspections and therefore approvals, we

have seen more competition on existing products than approval of new products. Third I'd say, some of the new wave companies that have gotten in whether it's Alkem, Alembic, others, they have gotten more aggressive in trying to get share at pretty low pricing. So, it's a combination of a couple of different things. Overall, just given the challenges that our customers also had this past year because of COVID. They've been trying to really make up for it in terms of the losses that they had, the margin loss they had by trying to really gain on the generic front.

Overall, as we look at our product mix, when we look at the last couple of quarters before Q1, with the ramp up of new products that offset older products, one feels pretty good about the ability to continue to increase both revenues and margins. In this quarter, there have been a few unanticipated events. Also, from our perspective, the transition on Albuterol has taken a little bit longer, albeit fairly confident of the ramp up.

**Saion Mukherjee:** Okay. I mean if you exclude Famotidine and the dynamics around Albuterol, the other base business- what has been the YoY price erosion or QoQ price erosion approximately?

**Vinita Gupta:** 4-5%

**Saion Mukherjee:** That's YoY?

**Vinita Gupta:** That's right.

**Saion Mukherjee:** Okay. And just one last question from my side before I join back. In opening remarks, there was a mention about possibility of spinning out of NCE research, biosimilars and specialty. I just wanted to get a sense of what you're thinking here, and Vinita mentioned around US\$20 million annual impact on EBITDA from specialty. Can you quantify for Biosimilars and NCE research as to how much of a drag is that on your EBITDA?

**Vinita Gupta:** Each of them are roughly around US\$20-\$25 million totaling around US\$65 million with the NCE being at 25 - 30 depending on how we progress our pipeline. US\$20 million each on specialty as well as on the biosimilars front.

**Saion Mukherjee:** Okay. And anything on your timelines and what you are exactly thinking. Are you trying to raise capital here separately? Anything you can share on your plans here?

**Vinita Gupta:** Sure. On the oncology front in particular, we've created Lupin oncology in the US with the idea of bringing in third-party investors, mitigating our spend/burn. Over the next 12 months to 18 months, looking to find ways and means of raising additional capital as we progress our pipeline. We have two programs - our lead programs that are going through IND enabling studies. As we file INDs in the next 12 months, that will be the right time for us to do a major capital raise around the oncology assets.





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- Moderator:** Thank you so much. The next question is from Mr. Anubhav Agarwal.
- Anubhav Agarwal:** Hi, one question Vinita is on Famotidine to start with. Now whatever was, let's say the earlier level for us after two players entering and price erosion happening, how material this will be product for us? Would you say this would be less than 5% or just around 5%? I'm not asking for numbers, but just trying to get a sense because don't want to see another quarter where sales are down, and everybody gets surprised?
- Vinita Gupta:** I don't want to quantify the number, that is really sharing competitive information, but it is a material product for us Anubhav. Not as big as it was, we certainly did not expect two competitors. We were expecting one competitor to come in but were surprised with the second. However, have retained 60%- 65% share on a very profitable basis and continues to be a material product for us.
- Anubhav Agarwal:** Sure, and now if you look at our quarterly sales, Famotidine really started ramping up for around 4Q '20, 1Q '21 quarter for us. So, if I subtract from 172- Albuterol let's say just assume some number, so if subtract that effectively. And if I were to take off Famotidine as well, our base business have been completely significantly impacted more than 4%-5% that you mentioned because 172 let's say give and take your minus 15 for Albuterol, you minus another 10 for Famotidine then our base business should have declined significantly more right. Let's say, a year back or let's say 4Q '20 level. Of course, there is no growth, but I see a myself decline there.
- Vinita Gupta:** That's right. We did see a base business decline over the last year especially related to our supply challenges.
- Anubhav Agarwal:** And when do you see this, let's say 172 number, which quarter for example, I'm just trying to get it out sense, where do you see this business getting about US\$200 million mark. Would it be like second half next year or do you expect earlier than that?
- Vinita Gupta:** We are hoping Q3 onwards.
- Anubhav Agarwal:** Q3 of this year or when do you have Suprep launch next year Q3.
- Vinita Gupta:** No, we are thinking Q3 of this year.
- Anubhav Agarwal:** And that will be largely driven by Albuterol ramp up or is there any of the product. You've mentioned Perforomist in the past but is there any other big launch that you expect?
- Vinita Gupta:** It's largely due to Albuterol ramp up, Brovana AG contribution, as well as increase in line product share that we have taken back again. It's a combination of in-line products plus Albuterol as well as Brovana AG. In terms

of material product launches, for the rest of the year - Sevelamer is one that we are planning to launch and looks promising to us. We have a couple of other launches that are smaller. Major contribution is still Albuterol, Brovana AG and our in-line products.

**Anubhav Agarwal:** Thank you. Just one last clarification. In this quarter, average market share of Albuterol, which would have been reflected in your number. What would you say because IQVIA now shows you're around 13% plus? So, what would have been a number, which would have been reflected in the spot. Yeah, I'm just asking percentage market share numbers would have.

**Vinita Gupta:** The percentage market share, like you said the IQVIA number of 13% is where we are at in terms of the prescription pickup. But when we look at the contracted share with our customer base, the long-term contracts, it's in the 18% to 20% range but its building up. This quarter's revenues don't reflect it, because we had some phasing off. One of our wholesalers bought in the last quarter and switching into the longer-term contracts, which started at the tail end of this past quarter. That's why you don't see the impact of that 13% within the quarter. I don't know if that was clear.

**Anubhav Agarwal:** Sure, thank you. I was expecting that this quarter would have reflected more like 7- 8% share which IQVIA shows or were you saying that you already had 13% but it was under the transition that's why it's not properly drifting?

**Vinita Gupta:** It's really under the transition from an inventory standpoint, from the wholesalers versus our longer-term customers.

**Anubhav Agarwal:** Thank you Vinita.

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

**Harith Ahmed:** Good evening. Thanks for the opportunity. My first question is on Solosec. We've recently had an approval for an additional indication there which is trichomoniasis. Does this materially change the revenue profile of the product? How should we think of the opportunity here? And on the commercialization plans for this additional indication, would we be incurring incremental SG&A for this?

**Vinita Gupta:** We were very pleased to get the indication approved. However, we have been very tight in terms of controls on our spend from marketing standpoint. Within those controls, the team did a stellar job of putting together a full new campaign that they launched around the trich indication. It was just launched a week before last. It was a successful launch and we are hoping that we see an uptick from this launch over the next couple of weeks, certainly in the rest of August and September. We are very keenly looking forward to the uptick in scripts from Solosec and believe that this is really the material inflection that will determine how much we continue to invest in the product.

**Harith Ahmed:** Got it, and my second question is on the respiratory pipeline. On Fostair, we've announced approval in UK, just wondering what are the plans for the rest of Europe? Do we have launch timeline for the remaining geographies in Europe? And on generic Dulera filed last year. So, any timelines, you could share around this product and the patent situation with respect to the brand?

**Vinita Gupta:** On Fostair, very pleased to get that approval and we are gearing up to launch it. It's being manufactured at Coral Springs, as we see to launch the product hopefully later this month. The rest of Europe, we have plans in place and partners in place to launch in Germany, France, Italy, and Spain and that will happen in the next fiscal year. This fiscal year, we intend to really maximize the UK market. The rest of Europe is going to be next fiscal year.

On Dulera, we have a CRL pending from the agency. But really strong communication going on with the agency in terms of our filing and what additional information/data they need from us. We expect to respond to that CRL later this fiscal year. We had filed one strength first and the higher strength later. Our priority was first to file the higher strength and then prosecute both together. We intend to respond to the CRL later this fiscal year. There is no patent on the product, so there is no IP hurdle on the product.

**Harith Ahmed:** Alright, Got it. That's all from my side. Thank you very much.

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

**Nitin Agarwal:** Hi, thanks for taking my question. Vinita, on the biosimilars business, what are thoughts now for our PEG filing? I presume the FDA inspection would be required now since. Any visibility on that and then where do we go beyond PEG now?

**Vinita Gupta:** Very excited with the PEG filing and FDA accepting the file. We do believe the inspection will be required. Just based on what Nilesh said, the FDA has started doing inspections through the local office in India. We hope that they can get to Pune to inspect our site sooner rather than later. Depending on the timeline of the FDA inspection, we hope that we are in a position to launch Pegfilgrastim in the US next year.

Beyond Pegfilgrastim, we are also working on on-body product. That is making good progress in terms of development and expect to file in the next fiscal year, based on the current timelines. That would be an attractive product on the biosimilars front. We have Ranibizumab that is progressing in our Phase III study. It's slowed down a little bit because of COVID in terms of recruitment, but still progressing. We have other programs like Denosumab, and which come in later, bEYLEA, which follows Ranibizumab on the public front that we are working upon beyond Pegfilgrastim and Ranibizumab.



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- Nitin Agarwal:** The initial comments around carving out biosimilars piece along with specialty and NCE. I mean your thought process; will you carve out all of these three pieces into a separate business or they will be three separate pieces which you've carved out? What is broad thought process around these carve outs?
- Vinita Gupta:** Our thought was really areas that need longer-term investments and are a burn on our P&L right now, but that we believe can deliver a lot of value to the organization. Biosimilars in particular, we feel is going to be a big part of the future of the generic business. So, from our perspective an essential investment. But when we look at R&D spend, we look at these three areas and granted that specialty is not R&D spend, its more a commercial spend, but investment in areas that our peers don't have for the most part. Really trying to find more creative ways to be able to bring in additional partners - financing partners to be able to mitigate the risk, spend and burn on the company P&L overall, but still have the ability to grow these areas effectively. Make the right investments from portfolio standpoint is the reason why we're looking at all three areas. That's not to say that we will necessarily do each, but we are exploring each to see what's the best way is to maximize value for the company by mitigating the P&L.
- Nitin Agarwal:** Got it. And lastly on that with the timeline?
- Ramesh Swaminathan:** We are still thinking through all of that, it's not as the plans are finalized or anything of that kind.
- Nitin Agarwal:** I mean I was just asking, is there any timeline to it, but I presume you're still thinking through it.
- Vinita Gupta:** I think the one that we've made most progress on so far is the oncology. Lupin oncology that we've created in the US with our pipeline assets, with the idea of attracting and bringing in the right investors that can help build that pipeline for bigger inflection close to IND filing, that I explained earlier today. That's the place where we made the most progress in terms of working towards carving it out.
- Nitin Agarwal:** Thanks, and best of luck.
- Moderator:** Thank you. Next question is from Mr. Tushar Manudhane.
- Tushar Manudhane:** Thanks for this opportunity. Just a clarity on this failure to supply. Is it to do with the issues at the manufacturing operations level or to do with some compliance aspects?
- Vinita Gupta:** It's primarily to do with COVID related supply disruptions that we had last year.



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- Tushar Manudhane:** Okay, it seems to get normalized in the coming quarter itself, or do you think this will get extended?
- Vinita Gupta:** No, we cleared all the supply penalties this past quarter.
- Tushar Manudhane:** Got it, and in the annual report it's mentioned about there's some 11 US litigation settlement in FY '21. All this is to do with the product-specific litigations, right?
- Vinita Gupta:** Yes, the P4 litigations.
- Tushar Manudhane:** Any further clarity on when the commercial traction can be expected from these?
- Vinita Gupta:** It varies product-by-product. Our team does a very good job of trying to determine what to settle based on our position in a particular product and what to prosecute from P4 standpoint to try to open the market as soon as possible. So, each product is a different case.
- Tushar Manudhane:** Okay. I mean to ask if anything specifically in FY '23 or it would be beyond FY '23?
- Vinita Gupta:** We are constantly filing new P4s well. Like last quarter, we filed three products out of which we were first to file in one. I think that all three of them are P4s. We have a pipeline of products where we have P4 litigation ongoing that we continue to prosecute, and the settled ones that makes sense for us to settle based on our position and our likelihood to succeed in a particular litigation. As we find new products, we have new P4s that we litigate.
- Tushar Manudhane:** And just lastly on Spiriva, so we are on track in terms of ANDA review, any update there?
- Vinita Gupta:** We are in the process of putting everything together for a CRL response in September. On track for that and hoping that based on that response, we will get an expedited review. But feel good about the fact that we can launch the product in next fiscal year.
- Tushar Manudhane:** And similarly, on the litigation side as well. The previous quarter, it was mentioned that it will be more or less starting in September, the litigation as well. What is the timeline there?
- Vinita Gupta:** We are tracking well on that front as well.
- Tushar Manudhane:** Good, thank you very much.
- Moderator:** Thank you. Next question is from Mr. Kunal Randeria.



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- Kunal Randeria:** Good evening, and thanks for giving me the opportunity. You said that you aspire to go to around US\$200 million a quarter from third quarter of this year in the US, but are you factoring in some competition, let's say in Levothyroxine or Fosrenol?
- Vinita Gupta:** We have already seen the impact of competition on levothyroxine not as much as on lanthanum. Based on where we are with Albuterol, where we are with Brovana, where we are with the pricing pressure around Famotidine, Levothyroxine, Glumetza, the additional business that we've been able to take on the in-line products, we feel good about growing our business quarter after quarter from this US\$172 million base here in Q1.
- Kunal Randeria:** Sure. So more specifically, even if, let's say competition does come in, more competition does come into these two products, you can still touch US\$200 million?
- Vinita Gupta:** I don't know specifically about Lanthanum, but we feel like we have seen a good number of hits in the first quarter and feel good about a ramp up in Q2 and Q3, getting to US\$200 million in Q3.
- Kunal Randeria:** Sure. My second question is on US itself, but slightly longer term. So, you have 18 exclusive FTF. In the next two or three years, how many do you expect to launch?
- Vinita Gupta:** We have a number of products in the next couple of years. The big ones that come to mind for next fiscal year are definitely Spiriva being one of the largest, Suprep is another major one. Lenalidomide is another one that we believe we should be able to launch next year, though we were not first to file there, still a very material product. So, a few material products next fiscal year.
- Kunal Randeria:** Sure. Just one more if I can squeeze in. What are your thoughts on biosimilar pricing also for example on Pegfilgrastim, innovator has been extremely aggressive and putting pressure on biosimilar players? So, wondering what your thoughts are, how do you see this market evolving?
- Vinita Gupta:** As I mentioned earlier, in the long-term, biosimilars is really going to be the future of generics, just given the percentage of the market that is in Biologics. So, it will operate very much like Generics from my perspective. Their time to market is going to be key and cost of manufacturing is going to be key. The companies that really are in the first wave of launches are going to be the ones that will succeed the most. I think just given the focus on bringing the cost down, you're going to see a pricing pressure also on the biosimilars just like any other generics. One will have to continuously bring in products, pipeline that offset the price erosion in all the products and ensure that strong focus on cost of goods to stay long-term.



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- Kunal Randeria:** Got it, Thank you very much.
- Moderator:** Thank you. Next question is from Mr. Sameer Baisiwala.
- Sameer Baisiwala:** Thank you so much and good evening everyone. You had also guided for EBITDA margins for fiscal '23 that's next year, if I remember correctly, was 21-22%. So, any change to that?
- Ramesh Swaminathan:** We are now talking about the current year, but we would like to endeavor to get to those levels. It's still in the works. Would keep you posted about any developments on this as we go by.
- Vinita Gupta:** I would just add to that. Obviously as you saw last year, our team worked very hard to deliver EBITDA improvement and we're very committed to it, despite the challenges in the first quarter. As we deliver in the second half like Ramesh said, the 17% to 18% level that will give us better comfort, better confidence. Just given the initiatives that we have underway to improve both our US generic business, as well as the other efforts around cost containment, we are very focused on getting to that 20% plus.
- Sameer Baisiwala:** Okay, that's very comforting. The second question is, the mention about the spin-off intentions, but I wonder if any of these three have any sort of scale for you to be able to spin-off this one. More specifically for onco portfolio, what exactly do you have in that portfolio that you can monetize over next 18 months?
- Vinita Gupta:** On the onco portfolio, we have five pipeline programs in the portfolio, two of which – a STING Agonist and a PRMT5 are undergoing IND-enabling studies right now. They're very attractive targets and we have fairly differentiated programs in those targets. As we are having conversations with potential partners, it gets a lot of interest from our perspective. Our breadth of pipeline, the five programs and then the ability to bring additional programs through the capabilities that we've established in our NCE group in India has been very well received so far. So early days until we start the journey of bringing in third parties. But the effort has started there and at least from a portfolio standpoint, the five programs and the lead programs have gotten a lot of interest.
- Nilesh Gupta:** If I could just add, even for the past, with the MEK and the MALT; these are moving extremely well as programs, a lot of our focus on Drug Discovery has been in the oncology space. It just seems to be the natural place to evolve for that structure.
- Sameer Baisiwala:** Okay and one final one. Vinita being the seventh or eighth company to settle for Revlimid, if you do at some point in time. Does it still make it an attractive market, and do you think with so many players, the pricing can still be good enough for everyone to make money?

- Vinita Gupta:** There are very few products at that scale. We believe the generics will launch in a staggered basis. I think that should hopefully enable a more rational marketplace, from what at least our team is looking at. With companies entering at different times, different level of share targets should really enable the product to be a very strong product for all the generic competitors.
- Sameer Baisiwala:** Okay. With your permission one final sorry. Can you update us on your filing for complex injectables - Peptides, depots, liposomals?
- Vinita Gupta:** Maybe I can start, and Nilesh, please add. Making good progress on multiple fronts. On the depot injectables, we have our first program Risperdal Consta in the clinic right now. We are hoping to successfully get it through the clinic over the next year or so and then file. We believe that we are one of few companies with the product in the clinic. Very excited about the opportunity. Paliperidone is following that one. On the liposomal products, our partner ForDoz is making good progress on Doxil, with the intent of filing it later this fiscal year. Ambisome is planned next fiscal year. Both are on track despite couple of months of delay due to COVID, but still on track for filing in terms of this fiscal year as well as next fiscal year. We're also making progress on our peptides as well as the iron colloid product out of India. I would request Nilesh to elaborate.
- Nilesh Gupta:** Thanks, Vinita. We roughly expect about four filings on the injectable side this year, coming out of the India stable. Exhibits for at least two peptide products in this fiscal. Like Vinita said, on the iron product as well, we'll take an exhibit and probably file shortly in the next fiscal. I think our pipeline, we've consciously tried to stay away from the conventional products on the injectable side, focusing on the ones which do have some level of challenge. I think the depot injections are the furthest end of the challenge. There too we have products in the clinic now. On the regular injectables also, at least four filings this year, likely six to eight filings next year. It's starting to get to a nice tempo.
- Sameer Baisiwala:** Thank you so much.
- Moderator:** Thank you. Next question is from Mr. Vishal Manchanda.
- Vishal Manchanda:** Thanks for the opportunity. My question pertains to the biosimilar business. So, when you launch Pegfilgrastim in the US next year would that need you to invest into a sales force commercial infrastructure? And would that be upfront. So basically, will there be additional cost pressures on account of that?
- Vinita Gupta:** It will require investment in a commercial team, small team that one would need to really be able to contract with the GPOs. Some we already have for injectables, but we'll need to bolster it on the biosimilars front. We will





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manage that very carefully to make sure that it's not quarters ahead of product launch, it's close to product launch.

**Vishal Manchanda:** Got it. And second, on overall Capex that you would need to do for funding your biosimilar business over the next three years. You have multiple biosimilars in clinics -- would each of these require a separate facility, and how much investment would go into that?

**Nilesh Gupta:** We're actually pretty good on the biosimilar Capex. There was a major expansion that's happened in the last year. It was still commissioning it. I think we have world-class capacities now on biosimilars, both on the mammalian side and microbial side. There is a little bit on the microbial side that we will add when we commercialize products like Ranibizumab. But we're pretty good on the capacity. I'm sure there will be some incremental capex, but certainly not a separate facility for each product.

**Vishal Manchanda:** Got it. And finally, on Enbrel. Any color on market share that you have been able to achieve in Europe?

**Vinita Gupta:** Single digit right now and still launching into multiple countries.

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

**Shyam Srinivasan:** Thank you for taking my question. Shyam Srinivasan from Goldman Sachs. Just the first question on the COVID portfolio, I missed the growth rate excluding COVID in India. I heard the number is 32% but is that right or India -- just grew 27%, so I'm just trying to understand what's the number?

**Nilesh Gupta:** I can take that. As you know, the acute is where the real growth happened in the Indian market. The Indian market grew by 39.2% including the COVID therapies, and 32%, excluding those. The chronic market grew 19.4%, while our chronic portfolio grew 22.6%. The acute market growth was 43.1%, without the COVID therapies. We grew 45.4% on the acute side. But if you add the COVID therapies in there, the acute market grew 52.5%.

**Shyam Srinivasan:** Okay. So, Nilesh just trying to understand what you have got in COVID in your portfolio, is there anything that you're quantifying?

**Nilesh Gupta:** As you know, wave two was terrible. We all know that. There was a very rampant increase of medicines which were used, perhaps off level as well. We even saw an increase obviously. Budesonide was part of the treatment protocol, so we saw a significant increase in Budesonide. We saw significant increase in anti-infectives in general as well. Even so in vitamins, steroids, dexamethasone we have a nice product. On steroids, we saw a significant increase as well.

**Shyam Srinivasan:** Got it. So, you're not quantifying a number right, Nilesh?

- Nilesh Gupta:** No, it's still smaller for us versus some of the other guys.
- Shyam Srinivasan:** Fair enough. Second question, just maybe this is coincidental, but looking at the mix of geographies now India's like 42% and US is 35%. Does it, obviously there is some element of COVID, which is probably go back, but just from a capital allocation perspective, how are we thinking about things? Do we need to allocate more to India and just link back question to the 17% kind of growth you expect to grow high teens- let's assume and maybe market participants put at 10%, 11% for the industry? So just curious on the drivers of the growth either in terms of price, volume, new product introduction. If you could help us?
- Nilesh Gupta:** Sure. Right now, as you know, the US is extremely depressed in the number. It's been a bit of a perfect storm in Q1. You will see that starting to repair in Q2, Q3 onwards. You'll see the saliency of the US going back up, and the saliency of India coming down correspondingly in that. I think the saliency is also reflective of the one-time NCE Income. When you take that out of the constituent set, the percentages change. These two are our big markets. I think for the US, the focus very much has been on R&D, and capacities, the pipeline to deliver for that. That focus continues.
- We've brought in a lot more focus in India. Firstly, on manufacturing where we added facilities like Sikkim which we've completely scaled up. But I think we haven't done a great job of pipeline in India. I think we've done a fantastic job of partnering a pipeline to bring in India, but I don't think we've done a great job of building a pipeline. That is where the focus is, that was also one of the key result areas for last year. We now have more than 20 products in development. At least four of them will come to market this fiscal and we should have 10-12 kind of unique products coming from our own stable into the Indian market next year on. I think these will obviously be a meaningful growth driver. Doesn't change the story from still getting access to in-license products and the like, but there is a significant investment, which is being made for even some of the new age COVID products. Other than that, just products that would fit into the respiratory space, into the cardiovascular space, into the diabetes space.
- Shyam Srinivasan:** Got it. Last question on the rank order of margins, I think, Ramesh made a comment that after the FTS, the US margins fell. I'm just trying to understand with the mix where it is? India being higher would have expected higher gross margins said or is my understanding incorrect there?
- Nilesh Gupta:** The gross margin in the US is higher but there are some line expenses which come in below, but Ramesh, would you like to add some color?

- Ramesh Swaminathan:** What you're saying is absolutely true. The US is generally the most profitable market from a gross margin perspective also. You just mentioned the fact that the salience of India was higher, this is only for the first quarter, and obviously that meant that the margins were compressed to that extent
- Shyam Srinivasan:** Got it. Thank you, and all the best.
- Moderator:** Thank you. Due to time constraints, we will just take the last question. Last question is from Mr. Surya Patra.
- Surya Patra:** Thanks for the opportunity. Most of the questions have been answered already, but just on the kind of overall margin front and the R&D spend front. So, the lowering of the margin is surely it seems coming from the US. Is that right? And in terms of R&D spend, it was indicated that it is likely to see a kind of some sort of moderation. In terms of percentage, obviously it has moderated over last couple of year period, but in terms of absolute number, if you see, it is still higher. Going ahead, the margin concern that we are building, is it just because of the kind of pricing adjustments in US or it is elevated R&D that we are thinking about given the pipeline that we are talking about?
- Vinita Gupta:** Definitely the margin pressure we saw was primarily due to the US. R&D spend was obviously a little bit higher than the previous quarter. As we look at ways of optimizing our US generic business and of the R&D spend, US generic R&D spend is the largest part, its 70% of R&D spend. We are moderating R&D spend to prune out tail-end products where the opportunities are marginal. We are working on optimizing R&D spend as well in line with US generic business P&L.
- Surya Patra:** It would be in the range of 9% what earlier it was indicated, or it is like to see some kind of moderation or some sort of elevation coming up generally.
- Nilesh Gupta:** I think the intention right now is to hold on to that R&D number as an absolute number. Obviously as we get top-line growth, if we are able to hold that number then as a percentage of sales, it will stay at that 9% odd level.
- Surya Patra:** Sure. Thank you, Sir.
- Moderator:** Thank you. I now hand over the conference to the management for closing comments.
- Dr Kamal Sharma:** Hello, Thank you everyone. Thank you for your participation and your interest in the company. We really appreciate your questions. Look forward to seeing you in the next quarter again. In the meanwhile, look after yourself, take care in these turbulent times and wish you all the best.



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**Moderator:**

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