



“Lupin Limited Q1 FY2021 Earnings Conference Call”

August 7, 2020

MANAGEMENT:

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Moderator: Hello Everyone, good day, and welcome to the Lupin Limited Quarter-I Financial Year 2021 Earnings Conference Call. Please note all participants lines will be in the “listen only” mode and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded. Thank You.

Dr. Kamal Sharma: Hello friends, this is Kamal Sharma It is my pleasure to welcome you all to Earnings Call for Q1FY21. I have with me Vinita, Nilesh, Ramesh Swaminathan, Arvind Bothra and Rajiv Pillai.

As you would have already seen that this has been a rather subdued quarter for us. You would get to hear reasons and our programs going forward, but primary driver for this performance have been adverse product mix and many COVID related impact in terms of costs which may be one time and impact on sales in many of our geographies. We certainly have our homework cut-outs for ourselves. Just to walk you through the details of the financial numbers I will request. Ramesh to do that for me & then the floor will be open for Q&A. Thank You, and over to you, Ramesh.

Ramesh Swaminathan: Thank you, Dr. Sharma. Dear friends, welcome to our Q1FY21 results webinar. This is the first time we are conducting the results discussion through the digital platform and I believe that if we find this suitable, we will continue this format in the subsequent quarters as well. Let me take you through the key aspects of our Q1 performance. We had already guided for a tough quarter, because we had felt the tremors of the same, due to the impact of COVID-19 in May itself. We felt that the impact of market disruption could be across all the regions including two of our largest markets, India, and the US. However, our API business outperformed this quarter. At Rs.3,468 crores, overall revenues were lower than the previous quarter by 8.5% and lower than previous year by 9.1%. The US business performed steadily at US\$ 180 - 190 million over the whole of last year. We saw this reaching US\$ 212 million in the last quarter i.e. Q4FY20. However, the US sales declined by 26% sequentially and 28% YoY to US\$ 157 million. This was because of demand contraction by 12% versus the previous quarter and over 6% vis-à-vis the previous year. The seasonality factor also played in and therefore we saw loss of sales in the Oseltamivir, Azithromycin & Cephalosporins business and there is impact of Metformin as well. In India, where we have consistently performed over several quarters, there was COVID impact and India region branded formulations declined 6% YoY, especially the acute products. As per IQVIA, Lupin’s growth in Q1 was -1.4%, whilst for the IPM it was -4.9%. In June, there was some demand revival but there was disruption again in July. But we do expect Q2 to be much better than Q1 as demand picks up again from August. As said before, API sales showed significant growth of 24.5% sequentially with strong positive momentum on demand



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as well as pricing. We expect the strong double-digit growth YoY to continue. On the gross margin front, we did well to actually sustain it at 62.9%, and this despite the fact there was sharp decline in US business as I had stated before, and also the impact of higher freight cost. But all the same, we were able to maintain the margins underlined improvements in overall business. Manpower cost increase in this quarter is on account of one time spent in terms of specialty restructuring in the US and COVID linked incentives. However, we do believe from Q2 onwards, we would expect the recurring benefits due to the specialty restructuring and we expect the overall absolute number to be lower than Q4FY20. Overall, on the manufacturing & other expenses, including the freight (the freight element was captured in terms of gross margins itself), expenses were higher by close to Rs.100 crores. However, there was significant fall in manufacturing & other expenses in terms of travel, legal & consulting fees, sales promotion expenses and the like. As you would recognize it was not possible to call on doctors, so there was considerable saving on that, promotions did not take place and so on. It is not necessarily something wholly sustainable but having said that it would be our endeavor to take digital means and try to sustain it at levels which are lower than the past. As we normalize the operations, we do expect some increase in the SG&A expenses but the savings to some extent will certainly continue. On the EBIDTA front we are happy to report an operating EBIDTA improvement of 1% over the last quarter but recognize this is without including FOREX and other income. We are confident that this EBIDTA trajectory will continue to improve in Q2 and beyond. I had guided for close to 19-20% which included other income and Fx impact as well, but had also added a caveat that this is before taking into account the situation on account of COVID. We re-evaluated the entire thing and we do believe that we should be to able to close at about 17% without any impact of FOREX or other income. In terms of the outlook we expect operating margin to improve, as we expect market share expansion of Levothyroxine and relaunch of Glumetza before the end of Q2. Additionally, customers start their winter buying and this should help products like Azithromycin, Cephalosporins and, Oseltamivir. Further, we look forward to the much-awaited launch of Albuterol in September-20. In addition, we have also partnered for a few products that we will be launching in next couple of months. Aided by tight control on manpower costs, SG&A expenses and rationalization of costs on the specialty front, we believe that we will be in position to boost the margins. In terms of the ETR which has been a sore point, it remains high this quarter, but we expect this to improve in H2FY21 with ramp up in sales and the specialty restructuring. For the full year we believe that ETR would be between 35% – 40%.

With this we would like to open the floor for discussions.



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- Moderator:** Thank you very much. We will now begin the question and answer session. Anyone who wishes to ask a question may “Raise your hand” from Participant Tab on your screen. Participants are requested to use Headphone/Earphone while asking a question. Ladies and Gentlemen, we will wait for a moment while the question queue assembles. As soon as someone “Raise Their Hand” to ask a question, the Lead Operator will enter the Conference and announce the participant name. Thank You.
- Arvind Bothra:** The first question is from Neha Manpuria from J P Morgan.
- Neha Manpuria:** Thank you so much for taking my question. My first question is on Levothyroxine. We have seen competition coming to the product, some of our peers also indicated price erosions. So, what sort of opportunity do we see? Are we still confident of market share ramp up in Levo?
- Vinita Gupta:** Yes Neha, we are well on our way to ramp up our share with Levo. There certainly have been a couple of new competitors. Some just switching like Lannett for Amneal. Recently we learnt about Strides. But if you look at the Levo market over the last five years and look at new entrants, especially the small entrants into the market, it is not an easy product at all to ramp up. It really takes a combination of strong delivery from supply chain standpoint, position from a manufacturing standpoint that is different from a typical oral solid product. So, while we see some additional competition, we still see a significant opportunity in Levo and as I mentioned we are well on our way to ramp it up.
- Neha Manpuria:** Vinita what would be our market share in Levo currently? And what would be contracted share against where we are?
- Vinita Gupta:** Right now, contracted is 12%.
- Neha Manpuria:** This can get to higher levels let’s say high teens?
- Vinita Gupta:** Yes, we hope to get it to high teens.
- Neha Manpuria:** My second question is on Metformin, sorry I missed it in the opening remarks. But is the recall included in the first quarter number and did I hear it correctly that this should come back by end of the second quarter?
- Vinita Gupta:** That’s right, the recall was included in the first quarter number, the best we could in terms of reserving. In the end of second quarter we expect to get it back into the market.
- Neha Manpuria:** The recall related cost, and any potential failure to supply penalties, would that also be reflected in the first quarter or you could see some more of that in the September quarter?



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- Vinita Gupta:** We have tried our best to create a reserve for it, and the impact of that we have taken in the first quarter. Hope that there will not be any incremental impact of the recall in the second quarter. But, getting the product back into market will help us get some upside from the product.
- Neha Manpuria:** Okay, Thank you.
- Arvind Bothra:** Thanks, I would request participants to call out where they are calling from - Which firm? And to ask only two questions, you can always get back in the queue so that others get a chance. The next question is from Shyam Srinivasan.
- Shyam Srinivasan:** Hello, Thank You for taking my question. This is Shyam Srinivasan from Goldman Sachs. The first question is on the India Business. You called out some qualitative color to help us understand the commentary around July being slower than June and we are just in first week of August, but what gives you the confidence that we will start to ramp this business again?
- Nilesh Gupta:** Sure, Shyam. We saw some of the COVID related stocking in March which continued into the first couple of weeks of April as well. During the rest of April & May is where we saw a major reduction in footfalls into doctors and therefore a subsequent reduction in demand as well. If you look at IQVIA you see that curve with especially the acute, being deeply impacted in April & May, and then you see the improvement in June; it wasn't that impacted on the chronic side. Very similarly for us as well, May was bad, June we saw the increase. We saw that we could open up. We went all the way up to close to 90% of our reps being back on detailing. We went to a call average on north of six as well. Then as you know in July, there were a series of Lockdown across states, which again brought it down to probably ~70% of reps going and detailing. August has started off much better and we see increase. Typically, you would see that Q1 is a actually a strong quarter for the India business and Q2 is weaker than Q1 usually. We are currently forecasting growth in Q2 over Q1 and August certainly seems to be shaping in the right direction.
- Shyam Srinivasan:** Thank you, Nilesh. Any guidance for the India business for the full year?
- Nilesh Gupta:** We have always grown at double-digit and that is based on market growing at 8% - 10%. You have seen the trends, the market is possibly forecasted to grow anywhere between 0.2% to 5%. My personal feeling is we will probably end up at 5% to 8% as a company.
- Shyam Srinivasan:** Got it, Thank You. My second question is just on the freight cost, I think Mr. Ramesh called it out, is that Rs.100 crores? And across which line items would we see that number?



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- Ramesh Swaminathan:** I said that the total expenditure has increased by close to Rs.100 crores. There is of course the freight component that is captured in the gross margin line, but there are other line items which comes below that, including the manufacturing and other expenses. There is small component that has gone into manpower also.
- Shyam Srinivasan:** Got it, just wanted to clarify on the point of manpower cost, you said it will be lower than Q4. So, if I say Rs.760 odd crores to Q4, is that the right number I should be looking at?
- Ramesh Swaminathan:** Yes, so we are expecting it to be lower than Rs.763 crores which is Q4 number, from Q2 onwards. I am not accounting for any one-time expenditure we might undertake, but the base figure would not increase.
- Shyam Srinivasan:** Got it. Thank you so much and all the best.
- Arvind Bothra:** Thank you. The next question is from the line of Nithya Balasubramanian.
- Nithya Balasubramanian:** Hi Nithya here from Bernstein Research. One quick question on ProAir if you can update us on when you are expecting an approval in the US?
- Vinita Gupta:** Hi Nithya. We expect to get an approval anytime now, within August, and we plan to launch the product in September.
- Nithya Balasubramanian:** Okay, and in terms of capacities, do you think we have adequate capacities? And what sort of market share are you targeting?
- Vinita Gupta:** We have adequate capacities for our fair share of the market. We do 20% plus in all our important products. We will be very strategic about the ramp up with Albuterol, it is a very important and valuable product for us as well as the industry. We will be very thoughtful and prudent about the build.
- Nithya Balasubramanian:** Sure, how are you seeing the pricing shaping up in the market? We do have two generics and three AGs already in the market so how has the pricing been?
- Vinita Gupta:** It's been fairly stable, broadly because of the fact that until last couple of months there has been a huge demand - supply gap because of COVID related surge in demand. So, the pricing has been fairly stable.
- Nithya Balasubramanian:** The other question I had was on India marketing expenses, we heard a bit of commentary that these are likely to be lesser than what it was earlier. If you can throw a bit more color on the what kind of savings are likely to outlast this COVID crisis.
- Nilesh Gupta:** On the Ad/Pro, there is a significant reduction at this point of time, in terms of promotion to doctors and the like. Some of the savings which will not replicate are the ones which are related to field staff. When they are working from home, allowances and the like is what you can save which becomes a significant number. Obviously for



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the rest of the year there is a lot of stuff like conferences and many more which would not happen in all likelihood. Certainly, international travel to conferences would not happen either. So, there would be savings which would happen in the course of the year. But if you go beyond COVID, this has been a really great opportunity for us to embrace the digital. We have done 3,200 CME's to date; we have done 200 training sessions for our representatives. The numbers are huge. There is a very large wholesome embracement of all things digital at this point of time. I do not think that it changes the market completely, like I said, more than 90% of representative are back on job. Our call average is between 6 to 7 per day. So, there is a fair bit of the old which is coming back as well. It is a great opportunity to go beyond as well.

Nithya Balasubramanian: Understood, Thank you so much.

Arvind Bothra: Thank you. The next question is from the line of Sameer Baisiwala.

Sameer Baisiwala: Good evening guys, thank you for taking my question. Vinita any update on Solosec, how is it doing in market, and what's the way forward?

Vinita Gupta: We have restructured our commercial infrastructure on the Solosec front this past quarter. As Ramesh mentioned, we had an onetime impact based on that. As we were talking even in May, that the doctor visits in the OBGYN offices pretty much dropped off completely and were down 80% and we saw scripts bottom out in April. Since April, into May & June we have seen ramp up in scripts, 10% in May, 20% in June and are continuing to see that for the most part in July as well. We are seeing demand come back, though slowly. Leveraging also the recent wins with, Express Scripts, just in the last week we had another major win, Cigna put Solosec in a preferred position. We are trying to drive prescription growth as much as we can. The team is just very focused on trying to be as nimble as possible. As doctor's offices open, get in front of the physicians as much as we can; as of now it is just 10% of our physicians / doctor's office targets that are really open for face to face visits. So, majority of the interaction is still virtual. But what is very heartening to see is that the virtual engagement is having an impact in scripts growth. And we continue to work to drive that in the months to come. I hope that answers your question.

Sameer Baisiwala: Yes, it does. Thanks. And Nilesh just picking on your comment in the press release, you talked about it being a pivotal year for complex generic launch this year for your key assets. So outside of Enbrel, Fostair, Albuterol, is there anything else that you want to talk about? And also, it says that pivotal year for momentum in compliance? So, if you can update us on those four sites, thank you.

Nilesh Gupta: We've been investing in inhalation for the last six to seven years; this is the year that



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we start delivering - Albuterol approval and launch, Tiotropium approval. There are multiple milestones that we will hit on inhalation. There are other assets that are under development, filings as well. So, it's a critical year from the inhalation perspective. On biosimilars at this point of time, it is Etanercept from a launch perspective, which we intend to launch this quarter in Europe. By the end of the year, we expect to file our Pegfilgrastim as well. Again, multiple milestones in biosimilars that will be there. And then switching to the compliance, we've had a very solid first half. The inspections that we had in the first quarter, were all positive in terms of outcome and we had slated this ought to be the year of completely earning back our rightful space on the compliance front. Obviously, with COVID, and with the restrictions with the FDA not really being in a position to do audits, there's a bit of a limbo at this point on our OAI facilities. But I think the momentum is to continue and we are aligned with FDA in that, everybody wants supply continuity, everybody wants facilities that are compliant to be up and running. We're working with the FDA; we've made a lot of progress at sites. Somerset, we have already put up for re-inspection, Goa & Pithampur, both of these are possibly in the next month going to be ready for re-inspection. And we're going to really work with FDA to see what the best way would be. I don't think there's a stated remote virtual audit process. There is certainly a document review process, there is a mutual recognition process as well. We'll have to push the envelope and see what the best way will be to do it. But, again, from our own internal development, there's a lot of strength, which has been built on the compliance front. And we certainly expect to take this to the finish line.

Sameer Baisiwala:

Okay, great. Thank you.

Arvind Bothra:

The next question is from Anubhav Agarwal.

Anubhav Agarwal:

Hi, this is Anubhav from Credit Suisse. One question on Albuterol market. I just want to understand how is the market now? Where is the demand supply gap now? is it still acute or it is normalized?

Vinita Gupta:

It has normalized to Pre-COVID levels.

Anubhav Agarwal:

Okay, so should we now expect that when you launch it will be a normal launch where you launch at a discount to existing prices. , When you say the price has been stable, so largely generics, when they come, they come at a 20%-30% discount. Their pricing for two generics and three AGs is largely around the bandwidth level even right now?

Vinita Gupta:

Yeah, the pricing has been fairly stable for the players in the market. We obviously will have to earn our way into the market. But as I mentioned, we're going to be very strategic about it, it's a large product, material product. So, the typical 20% - 25% is not



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for larger products, one has to be more thoughtful about the benefit what you need to do to earn the business.

Anubhav Agarwal: Okay, and just on understanding this quarter US sales a couple of things to check. Apriso launch - did it reflect in this quarter? Or would it reflect in the next quarter?

Vinita Gupta: It reflected to a certain extent in this quarter and will continue to obviously reflect in Q2 and beyond.

Anubhav Agarwal: I was shocked with the US\$157 mn US sales. Was there any product literally outside the Metformin loss that we had, and the seasonality impact and when I'm including Azithromycin lower sales also, was there any other impact to the US sales in this quarter? Any particular product that we see significantly lower sales, which are non-seasonal?

Vinita Gupta: Yeah, with US\$ 157 mn we are very disappointed as well. But a part of it was demand contraction, also exacerbated by the fact that the market stocked up inventories in March right ahead of COVID or in anticipation of COVID. Just overall demand, even if you look at overall market; and for our specific products, we saw contraction quarter over quarter, because of the buys in March. Additionally, if you look quarter over quarter the biggest part of the drop was the flu season products - Oseltamivir, Azithromycin & cephalosporins, as Ramesh mentioned earlier, then Metformin and the demand contraction due to the pre-buys in March.

Anubhav Agarwal: So, at the product level other than Metformin and the seasonal impacts, there was no change in our product level impact in our portfolio.

Vinita Gupta: Not any material changes.

Anubhav Agarwal: Okay, thank you very much

Arvind Bothra: Thank you. The next question is from Nikhil Mathur.

Nikhil Mathur: Hello, this is Nikhil from Ambit capital. Just one question on Albuterol first, what gives you the confidence that finally the approval would be attained in this particular month and eventual launch would be in September. Is there a threat of a negative surprise on this front, that approval might be delayed again?

Vinita Gupta: No, we certainly hope not, Nikhil. We had expected to receive the approval by now, but there was a last-minute amendment that our API supplier made which took it out of July. Otherwise, we could have got in July. We understand, from the indications we are getting from the agency, that all the reviews are complete and that we should get approved pretty soon. We would launch only in September. Added level of confidence we have is our marketing POA to be able to prepare for launch has been accepted by



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FDA, so it gives us the ability to get the inventories across the border.

Nikhil Mathur: Okay, can you help us a bit more understand when you say that for certain larger products and Albuterol being one of them you will be a bit strategic about how to go about ramping up the sales of this particular product? So, what do you intend to mean by being strategic? So, does it mean that it would be more of a staggered approach that you will be gauging prices initially and then eventually go for a full roll-out.

Vinita Gupta: Yeah, we will obviously want to be able to be gain our share while ensuring the profitability and will weigh our options as we gain share to determine how best to do that. This is a good product in the long term, in the next few years for us and we will want to use the next couple of quarters to ensure we ramp up successfully, while not causing any material change from a pricing standpoint in marketplace.

Nikhil Mathur: One final question, so it's been talked about that EBITDA margin reversal should start happening from Q2 and sorry if you can repeat the guidance that what kind of exit EBITDA margins are we looking at in Q4. So just one question tied to this would be are there any explicit cost savings that are being budgeted for you to move up to say 17%-18% EBITDA margins excluding other income.

Ramesh Swaminathan: EBITDA margins are always a function of three things. Essentially, the kind of products we bring to the market, how much cost do you incur in terms of conversion and the like, various expenses in SG&A and so on. On the products front there are quite few products lined up. As we just spoke about Levothyroxine ramp up, we are speaking about Albuterol and the US business would bounce back in terms of kind of volumes that you see out there, and the kind of value you will see there. We have been indulging in cost initiatives for quite some time now. We have been working with different consultants in terms of alternate vendor programs and the like, and the impact of which will certainly be felt much more on the gross margin line as we go by. Apart from that we are also working on several initiatives to bring down the cost below the gross margin line as well, and on the R&D front we will do what it takes to kind of sustain the expenditure at the same levels or even lower as we go by. With all this we were fairly confident and at the beginning of the this year we guided to anything between the 19% - 20% and perhaps a little more than that, but then we also took a step back given the fact that there was this issue of the COVID. After having looked at that, we believe that we should be in position to look at least about 17% by the end of the year.

Nikhil Mathur: And this excludes the other income, right?

Ramesh Swaminathan: Yes, it excludes other incomes and FOREX.

Arvind Bothra: Thank you. The next question is from Girish Bakhru.



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- Girish Bakhr:** Hi this is Girish from Bank of America. First question is. on biosimilar Enbrel. As you are preparing to launch, will launch be across multiple countries or there are few select countries? I mean based on current capacity if you could share what sort of market share can we expect?
- Vinita Gupta:** The launch is going to be in Europe, in the next few months. Starting with Germany, which is the largest opportunity, that will happen this month. In the next quarter we expect Mylan to enter France, Sweden and couple of other countries. France will be the next major market and then follow into the other countries. So, it is going to be a build-up in share since this is a hybrid model, it's a hybrid play from a commercial perspective. As we look at what Mylan has done with other products, we certainly expect overtime for them to get to double-digit share.
- Girish Bakhr:** And Vinita, where would UK fit, I know probably will have to secure a separate approval, where would UK fit in this?
- Vinita Gupta:** UK is 3rd wave; Mylan has determined the launch sequence based on the size of opportunity as well as pricing.
- Girish Bakhr:** Okay, my second question was on the API front. I mean given you had a great quarter on the API growth perspective and knowing Lupin is pretty strong in the Ceph's & penicillin intermediates as well, are you looking at capitalizing on the potential opportunity that may come from PLI scheme?
- Nilesh Gupta:** We think that the PLI scheme is the step in the right direction, but it's a step. I think incentives are light at this point of time. There are six or seven products where we are reviewing very closely what we'd like to do. Some of it is connected to the PLI scheme, some of it is just connected to the fact that it's about time that we ramped up share in some of those, fermentation for example. Where there is over dependence on intermediates, you know, we are seeing an opportunity to be able to step up. We're going to have to work as an industry with the government in terms of tweaking the scheme so that, five years later we are actually genuinely able to say, this is what we did to reduce dependence. But other than that, I think, it's an opportunity for the API business in general. For the sector it's a great opportunity to earn back the space that we had, which we lost over the last 10 years, whether it's intermediates, whether it's fermentation, whether it's API. I don't think we're going across the board. But there are several sets of products where we feel that making the right investment will make sense now.
- Girish Bakhr:** Right. Just on that similar thought process, Nilesh or Vinita if you could just also comment on the Trump order which in a way not deliberately used towards mandatory



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but really preferring local manufacturing. I mean, at gross level probably, it looks like initially you will have some critical API's, but do you think in the longer run, this is like a challenge to overall Indian industry as well.

Vinita Gupta:

We actually think that overall, it's going to be an opportunity for our industry, especially for the larger players that have a foot from a manufacturing standpoint in both countries. From a near term perspective, we really see this very focused around essential medicines related to COVID, very focused around government buying. We get a very small percentage of the government business supplying out of India. In any case, because there is a preference for local manufacturing. This order, depending on how it's executed could mandate or give significant preference to local manufacturing on the government front which, from our perspective we see as an incremental opportunity. Based on the conversations that we are having with the government, they are very cognizant of the role that India plays in the US supply chain. They are highly focused on drug pricing as we have seen in the other orders. We, as an industry, have made them aware of the impact of manufacturing in the US versus India the cost impact. They understand this incremental cost impact. So, we do expect that this move towards manufacturing is going to be around areas of high national importance, which right now is COVID related products, anti-infectives and a couple of categories that the government has highlighted broadly. We'll find out, over the next couple of weeks and months, how this transpires into actual products but our expectation is again, it's going to be essential medicines, more COVID related in the near term, which will be an upside for us. Also, the government business opportunity will be an upside for us.

Girish Bakhr:

This was very helpful Thank you

Arvind Bothra:

Thank you. The next question is from Nitin Agarwal.

Nitin Agarwal:

Thanks for the taking the question, Vinita, on the Fostair launch in Europe as well as the Enbrel launch, especially on Fostair launch how do you see the market opportunity and how do you see the ramp up in the product going forward

Vinita Gupta:

It's a significant opportunity, Nitin. We expect it to be a limited competition launch. We expect to get approved at the end of this calendar year and launch in this fiscal year. It is going to be a ramp up because in our first country, UK, it's going to be a branded play. It's a significant opportunity for our UK as well as European business. We will launch first in UK in this fiscal year.

Nitin Agarwal:

On the Enbrel, given the fact that biosimilars in Europe have been extremely comparative from a pricing perspective, how should we look at Enbrel opportunity in this context now? Given the fact that Mylan's entry in the market is as a late entrant



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now?

Vinita Gupta:

If we see the performance of biosimilars, especially if you go market by market, the focus that Mylan has is on markets that are a bigger opportunity from share and profitability standpoint. We expect that they have the ability to get to the double-digit share in those markets. We're not going to look to get into every market, we're going to really look to get into markets that make the most sense from share gain and profitability standpoint.

Nitin Agarwal:

Nilesh, the remediation cost, if you are undergoing, are they a meaningful quantum on our cost side and once the plant issues get resolved, should we see a material impact on the cost going forward?

Nilesh Gupta:

Yes. While it has not increased over the last couple of years, there is significant remediation cost, especially some of the third-party consultant work, for example in Mandideep where we have a warning letter. So, those costs are ongoing. They are actually lower with COVID because everything is being done only remotely. We are now selectively reexamining, if you go deeper into our compliance issues, one of the big areas was investigations. I think we've been able to now start inspiring confidence in our actions on the investigations front and that gives us the opportunity on what is the best way to structure this, so that we take more of an internal lead rather than a third party lead for some sites. Other sites where we feel that we still need to have input, we continue to do that. We're relooking at the scope of third-party work. We're examining that very closely at this point of time. I would see a decline this year versus last year and then going forward it should come down even more.

Nitin Agarwal:

Thank you and best of luck.

Arvind Bothra:

The next question is from Harsh Beria.

Harsh Beria:

I'm professional investor from Switzerland. My question is, with the ramp up of the specialty and the biosimilar divisions, how do you see the top line moving from the current US\$ 2 bn levels in the next 5 to 7 years.

Vinita Gupta:

Yeah, so if I may take that Harsh, certainly see the potential on the back of the complex generics, biosimilars and specialty to really get to the consistent double-digit growth year after year in the next 5 - 7 years. From a portfolio evolution standpoint, we have significant opportunities starting with the rollout of a complex generic assets this year - Albuterol and Fostair on the inhalation front, plus, Enbrel on the biosimilars front, on the specialty front with NaMuscla which is ramping up very nicely as well in Europe. We are looking at the potential of getting it into the US market and building on Solosec on the specialty front in the US. As we look at the next couple of years, we have a whole



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pipeline of these complex generic assets and these platforms playing out after Albuterol and Fostair this year. We expect in the next year we'll have other inhalation products - Brovana that we are approved for, Perforomist that we expect to get approved for, Dulera that we have filed, and then Spiriva in the following year. So, the inhalation portfolio will play a material part in the next couple of years. On the biosimilars front with Enbrel starting this year, and full year impact next year, plus pegfilgrastim coming into the market in FY23, and you start seeing impact of biosimilars in the US and Europe over the next two years. And then the injectable portfolio coming thereafter. We really see all of the investments that we have made in the complex generic front, we are right at the inflection point to benefit from it in the next couple of years driving top line growth, hopefully on an annualized basis. But in a 5-year timeframe, double digit growth.

Harsh Beria:

Pretty comprehensive answer. A follow up to that, going forward, let's say 7 to 10 years ahead, do we think of spending more on R&D from the current 10% of sales revenue to maybe making it up to 15% to 17%, and also how do you see the margin trajectory for these products kicking in?

Vinita Gupta:

We believe that our R&D level is at a point from an absolute standpoint, that we should be able to manage within over the years to come. We are looking very hard at R&D investment. Obviously we want to continue to build our business based on the complex generic assets, which are a big part of the R&D investment, and we hope to be able to maintain it at that 10% or hopefully with revenue growth at below the 10% level. Definitely looking hard at that line, and likewise as Ramesh mentioned earlier, the other lines as we look at the EBITDA trajectory, with the complex assets improving our overall gross margin and our efforts on the operational efficiencies that we've already got some benefit from in the past year, but we are expected to get material benefit this year Little bit delayed due to COVID. We certainly will have that benefit FY22 onwards. Plus, all initiatives around manpower and cost containment, which you will see Q2 onwards, like Ramesh said. Our manpower costs will be below the Q4FY20 level. We are very determined to keep it under control and make sure that we are getting the right productivity, from a manpower standpoint. Likewise, on the SG&A front, we see some potential for improvement. We have seen some savings just as a result of COVID and COVID related cost. Travel and promotional costs will see some ramp up, but we certainly see a real opportunity to bank savings on that front as well. As we look at the impact of our portfolio and building up our revenues, with the complex assets, biosimilars, specialty, plus the strong control on the cost lines, in particular manpower and SG&A, and maintaining R&D at under 10% of net sales, we expect to



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get our EBITDA margin to the right level in the 20s.

Arvind Bothra:

We can move on to next question from Charulata.

Charulata:

Hello, I am from Dalal & Broacha, my question pertains to Metformin. Is the entire recall done with or there is some more to come? Secondly with the NDMA in Metformin, do you see doctors moving to some other molecules or combinations like it happened in the sartans?

Vinita Gupta:

On the first question, the impact for the recall has been provided as best as we could into Q1, and hope this was sufficient. We should not see any further impact in Q2. As I mentioned earlier, we hope to see some upside with the re-launch of Glumetza generic in Q2. We really don't see a switch of Metformin into other products because the NDMA issue impacted multiple players in the marketplace, it did not impact everybody. We ourselves have been able to work around the NDMA issues and that is why we have the confidence of getting into the market in Q2. The market has been supplied in the near term by players that did not have NDMA issue, so we don't see the market really changing in any material manner.

Charulata:

Don't you expect to see a major improvement in EBITDA margins after launching Enbrel in Europe

Vinita Gupta:

Enbrel is going to be a build-up. As I was mentioning earlier, it is a hybrid branded model and it's going to be a build-up of share,, not like a US substituted generic where you have an opportunity of taking major share day one; it will be a ramp up. It's a material opportunity in the next two to three years.

Charulata:

Okay, Thank you. All the best.

Arvind Bothra:

Thanks, next question is from Prakash Agarwal.

Prakash Agarwal:

Hello, Good Evening, Prakash from Axis Capital. I just want to know if we have called out from US\$ 200 plus mn to US\$ 157 mn, Have you given specifics like little bit color on the quantum of Glumetza loss of sales apart from the seasonality & the COVID-related you talked about, but any color on the size Tamiflu & Glumetza and when do we go back to US\$ 200 mn again. Would it be Q3 onwards? Some color would help.

Vinita Gupta:

Yeah so, we did not provide any more in terms of actual product numbers but roughly, what we said is of the US\$ 50 mn drop, Prakash, more than 50% was the flu products Tamiflu, Azithromycin & Ceph's and the balance was a combination of Metformin and demand contraction due to the pre buying in March. We expect in the next two quarters, from Q2, things will certainly improve as we are looking at the demand per say and the flu season products are also coming back into the market. We were doing US\$ 180 mn to US\$ 190 mn pre COVID and we will get back to that level & beyond, Q3



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onwards.

Prakash Agarwal: Perfect that is very helpful, Thank You. Second question is on USFDA side. Are we giving any color as a base case since we have already submitted for re-inspection for Somerset? When do we expect for a base case resolution & same for Pithampur & Goa?

Vinita Gupta: We have informed the agency that we are ready for Somerset. They are doing face-to-face on-site inspections in the US, but for Mission Critical projects first. We hope that we are going to be part of the Mission Critical. We have an Azithromycin supplement also filed from Somerset. We are hoping that will trigger inspection sooner rather than later. It's very hard to really predict the actual timeline for the efforts that we are making on COVID-related products, but hopefully it expedites things.

Prakash Agarwal: Okay, Perfect. Thank you and All the best.

Vinita Gupta: Thank you Prakash.

Arvind Bothra: Thanks, next question is from Kunal Dhamesha.

Kunal Dhamesha: Hi, Thanks for taking my question, so the first question is clarity on Albuterol. You mentioned that we are expecting 20% plus market share, so is it the 20% market share of entire Albuterol market or is it for the ProAir franchise?

Vinita Gupta: 20% is going to be a build-up, & we look at entire the Albuterol market not just ProAir. We targeted ProAir because it is the largest brand in the marketplace and allows us full access to the market.

Kunal Dhamesha: And second question is on the tax rate. The tax rate in Q1 was significantly higher and while you guided ~35%, so is there any change in the guidance now that we were significant high tax rate in Q1.

Ramesh Swaminathan: It will be little higher than what we have earlier guided, but it is certainly not going to be at the same levels as in the current quarter. It will come down significantly. We expect it to be anywhere between 35% to 40%.

Kunal Dhamesha: And for the future years, what would be the progression of tax rate?

Ramesh Swaminathan: It will be back to the 32% - 33% over time, for sure.

Kunal Dhamesha: Thank You.

Arvind Bothra: Next question is from Krishnendu Saha.

Krishnendu Saha: Vinita, you spoke about some marketing activities in the US for Albuterol which is approved by the FDA. Are there any contracts which you have on the verge of signing or you have contracts with people for Albuterol? And Nilesh, on the Levothyroxine expanded capacity which we have, what kind of utilization we have?



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- Vinita Gupta:** Yes, the pre-launch activities are on-going.
- Nilesh Gupta:** On the capacity utilization for Levothyroxine we have been building inventory in anticipation of off take. We are in a good position overall.
- Krishnendu Saha:** Any numbers or we're like good enough! That's what I can get.
- Nilesh Gupta:** Yes, it's good.
- Krishnendu Saha:** Thank You.
- Arvind Bothra:** And next question. We have a follow on from Nithya Balasubramanian.
- Nithya Balasubramanian:** Yeah. Hi, a very quick question on the partnership with ForDoz Pharma that you announced yesterday, if you can throw a bit more color on what these assets are, and are these short-term opportunities FY 22/23?
- Vinita Gupta:** Yes, sure Nithya. We are very pleased with the expansion/enhancement of our injectables portfolio. With this partnership with ForDoz, we have two products in the partnership, Doxil (doxorubicin Liposomal) as well as AmBisome. Doxil we expect it to be filed next year and AmBisome the year after, probably will be FY24 opportunity, but certainly a significant enhancement to our injectable's portfolio.
- Nithya Balasubramanian:** So, these are products that are likely sold through specialty pharmacies or do they require any additional capabilities when it comes to your commercial infrastructure?
- Vinita Gupta:** Yes, we have been in the process of building institutional commercial strength in the organization just given the portfolio that we are focused on. With all of the focus on the injectables in the near term, we have a few simpler products in the next two years, that are decent opportunity. Second, we have Pegfilgrastim that we expect to file this fiscal year and we expect to be in the market in FY23. We are building up commercial strength to be able to participate effectively, both on the injectables as well as the biosimilars. There is a lot of synergy on the commercial infrastructure for both.
- Nithya Balasubramanian:** Are you likely to commercialize the biosimilars in the US on your own or are you looking for partners to do that?
- Vinita Gupta:** No, we very much expect to commercialize on our own especially the first couple of products Pegfilgrastim as well as Ranibizumab. The kind of infrastructure we will have in place for our injectable generics, we can easily leverage that for those two products.
- Nithya Balasubramanian:** Thank You, Vinita.
- Vinita Gupta:** My pleasure.
- Arvind Bothra:** Next question is from Rishikesh Patole.
- Rishikesh Patole:** Hi, thank you for the opportunity. Vinita, just to follow on Albuterol one aspect you



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said was pricing is fairly stable, right. So, other aspect is interchangeability. So, as you mentioned, you are targeting the whole market, from the players that are already there in the market right now currently, is it going to be gradual interchangeability?

Vinita Gupta: No, we don't see the interchangeability gradual, especially for ProAir, which is the largest product of the market. If you look at the shares right now, the ProAir generics are doing pretty well. Also, the Proventil overall has taken a little more of the market, really at the cost of GSK, the Ventolin product, and it's AG. So, we see our ProAir generic giving us access to the entire market from an interchangeability standpoint.

Rishikesh Patole: Sure, and if you can help me with the branded revenue figure in Q1!

Vinita Gupta: Yeah, branded business was very severely impacted. As we had also mentioned in May, was down 45% - 50%. So, from the US\$ 4 mn base of Q4, it was US\$ 2.5 mn in Q1.

Rishikesh Patole: Thank You, that will be all.

Arvind Bothra: Thank you, we have the last question which is a follow on from Sameer Baisiwala.

Sameer Baisiwala: Yeah, Hi. Thank you so much. Is it okay to say that Albuterol authorized generics are being supplied from the branded company? So, the COGS are quite different from yours. And is there any other competitive difference between having in a pure generic verse an authorized generic as a competitor?

Vinita Gupta: To your first point. the authorized generics are from high cost facilities, primarily in the US. In fact, even the largest ProAir generic from Perrigo is from Catalent, which is an US facility, so a high cost facility. I believe that both we and Cipla have a real advantage with the product out of India. The fact that we have a couple of US manufacturers in the mix really helps us keep that pricing stable. You know, as we look at the market evolution over the next couple of years. Sameer, can you repeat your second question?

Sameer Baisiwala: Is there any other competitive difference with authorized generics, or is this the only difference?

Vinita Gupta: Some of the mail order in in the past have preferred keeping the brand, but when you have a couple of players, you typically see a switch. We certainly are looking forward to really accessing that market. Have seen a tremendous level of interest.

Sameer Baisiwala: Okay, one final one from my side, if I may, on Metformin when you go back to market you get all your market share back, all your customers back or is it rebuilding all over again?

Vinita Gupta: For the last five years, we have been such a strong player in the Metformin market, from a supply chain perspective, we have really built very strong relationship over the years and believe that we have the ability to regain our share. And, hopefully, we'll be



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able to regain, majority of it.

Sameer Baisiwala: Okay, great. Thank you so much.

Arvind Bothra: Thanks a lot. With this I would like to hand over to Dr. Kamal Sharma for closing remarks. Sir please.

Kamal Sharma: Okay friends, thank you very much for your participation. Hope you had adequate answers to your queries. Look forward to connecting with you again next quarter and in the meantime, stay safe and stay healthy and good luck. Thank you very much.

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