November 13, 2019

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,

Sub: Q2 FY20 Results Conference Call.

Pursuant to Regulation 30(2) read with Schedule III Part A(15) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Q2 FY 20 Results Conference Call on Wednesday, November 6, 2019 at Mumbai.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,
For LUPIN LIMITED

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

LUPIN LIMITED MUMBAI INDIA

Encl.: a/a

“Lupin Limited Q2 FY20 Results Conference Call”

November 06, 2019

MANAGEMENT: **MR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**
MS. VINITA GUPTA – CHIEF EXECUTIVE OFFICER, LUPIN LIMITED
MR. NILESH GUPTA – MANAGING DIRECTOR, LUPIN LIMITED
MR. ALOK SONIG - CEO – US GENERICS AND GLOBAL HEAD – GENERICS R&D & BIOSIMILARS
MR. RAJEEV SIBAL – HEAD, INDIA REGION FORMULATIONS BUSINESS, LUPIN LIMITED
MR. NARESH GUPTA – HEAD - API PLUS, LUPIN LIMITED
MR. SUNIL MAKHARIA –PRESIDENT (FINANCE), LUPIN LIMITED
MR. RAJIV PILLAI – SR VICE PRESIDENT, CORPORATE PLANNING, LUPIN LIMITED
MR. ARVIND BOTHRA – HEAD, INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED

Moderator: Ladies and gentlemen, good day, and welcome to the Lupin Limited Quarter 2 FY20 Earnings Conference Call. As a reminder, 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 signal an operator by pressing * then 0 on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to the Lupin management. Thank you, and over to you.

Kamal Sharma: Good afternoon, everyone, and welcome to this earnings call for Q2. Let me first introduce my colleagues here in the room who are here to answer your questions. I have Vinita; Nilesh; Alok Sonig, who heads the Generic Business in the U.S.; Rajeev Sibal, Head of India business; Naresh Gupta, the Head of API Plus business; Sunil Makharia; Rajiv Pillai and Arvind Bothra. I just want to start by saying that given the business climate, the competitive dynamics, the regulatory rigor and the development risk in the recent times given the business of complex generics, specialty and biosimilars, I think the company has turned out good results.

Year-on-year, the sales have grown by 10.4%, and the EBITDA has grown by 10.8%. On a half yearly basis, the revenue growth is 13% and the EBITDA growth is 20%. We continue to maintain EBITDA around 20% over the quarters, as you would've noticed. And the entire team is dedicated to strengthening the business. There are 3 legs on which we are doing this, continuously rationalizing and recalibrating our business mix, building in operational efficiencies and investing in specialty business which is the future of the company and the complex generics business.

With that, I would now hand it over to Rajiv Pillai, to give you financial heads up and then the floor will open for questions and answers. Thank you.

Rajiv Pillai: Thank you, Dr. Sharma. Good afternoon, friends. I will give you a quick overview of the financial results for Q2.

Sales for the quarter came in at INR 4,297 crores, which represent a 10.4% growth compared to the previous year. H1 sales were at INR 8,653 crores, which is a 13% growth versus the previous year. Notably, the sales line includes the licensing income from the contract that we entered with Boehringer Ingelheim. This time, we had 2 exceptional items, which are reflected in the results. Company agreed to pay US$ 63.5 million as settlement in connection with Texas lawsuit, of which US$ 53.5 million has been provided for. We only had a provision of US$ 10 million. During the quarter, we also recorded the divestment of our Kyowa CritiCare (KCC) business, which was a non-core, non-synergistic asset and non-value adding. This resulted in a loss on divestment of about INR 167 crores. EBITDA came in at 20.1% for the quarter and net profit before exceptional items was INR 258 crores. Our investment in research continues, and that is at 10.1% of the sales. And as we have committed, we continue to keep at the same levels as the previous years at under 10% of sales.

Nilesh Gupta: We'll open it up for questions now.

Moderator: Thank you very much. We will now begin with the question and answer session. The first question is from the line of Vishal Biraia from Aviva Insurance. Please go ahead.

Vishal Biraia: Sir, could you share your thoughts on the price erosion on the base business in the U.S., please?

Alok Sonig: The base business has stabilized in the U.S., the erosion is down to low single digit. And we feel pretty comfortable about the robustness of the base business.

Vishal Biraia: Any large launches that you're planning for second half of this year?

Alok Sonig: One of the key launches, which was obviously late last fiscal, Levothyroxine - will be ramping up as we look at the second half of this fiscal. We are looking at another 3 or 4 launches in balance of the year, which could be sizable.

Moderator: Thank you. The next question is from the line of Neha Manpuria from JP Morgan. Please go ahead.

Neha Manpuria: First, on the U.S. business. In the last quarter, we'd mentioned that Levothyroxine capacity would come on board towards the end of the year and that's when we'll see share ramp-up. So has that come on board earlier than expected, and we are expecting improvement in the U.S. in the second half?

Alok Sonig: Yes. Neha, thanks for that question. So, the supply has stabilized, and we've actually ramped up on or slightly ahead of schedule. The supply is looking pretty robust. And that's the basis for my comment that we should see a ramp up in demand and demand fulfillment for second half of the year.

Nilesh Gupta: We talked about the capacity expansion kicking in early in the next calendar year and we're on track on that too.

Neha Manpuria: Okay. So this capacity will still come on board early next year?

Nilesh Gupta: We've already had a ramp up and further expansion is underway.

Alok Sonig: So there's been a ramp up, just given choices we've took shutdowns on other products, which were less valuable and diverted that lines in favor for Levothyroxine. So that's really the ramp up in this fiscal. And then the next wave of the civil infrastructure expansion kicks in early in the next year. Supply is not going to be a constraint in other words.

Neha Manpuria: And my second question is on ProAir CRL. Are we still maintaining guidance of approval before fourth quarter FY '20?

Vinita Gupta: We feel pretty good, Neha, about our ability to respond to the CRL, pretty soon in the next month. And we hope that we can get approval before the end of the fiscal year. But certainly, expect to launch the product in the first half of next fiscal year.

Nilesh Gupta: So, first quarter, if we're lucky. But I think probably at the outside, within the first half.

Neha Manpuria: Understood. And my last question is on Solosec. Vinita, if you could give us some color on how that is ramping up and what was the branded sales in the quarter, please?

Vinita Gupta: The branded sales were flat quarter-on-quarter at US$ 5 million, primarily a big part of it is Solosec. In the other products, Suprax has a generic and Methergine has a generic, so that has been eroding. Quarter-on-Quarter, we've seen a 10% growth in scrips, so our weekly scrips have now crossed the 2,000 mark. That's good, it's in the right direction but a long way to go. I would say that we've made some progress, but more to come. We have a number of efforts ongoing. We have got a new leader in place, Jon Stelzmiller who joined us just a month ago with a very strong experience in women's health as well as a very strong experience in launching products successfully. We have multiple tactics from a targeting standpoint, from a pharmacy standpoint to ensure that we grow the scrips, grow the demand as well as don't have any leakage at the pharmacy end.

Moderator: Thank you. The next question is from the line of Anubhav Aggarwal from Crédit Suisse. Please go ahead.

Anubhav Aggarwal: One clarity on this Texas payment of US$ 63.5 million. Can you just roughly mention how much of the sales that we made here and which period does it pertain to?

Vinita Gupta: It pertains to period prior to 2012 and Texas was substantial part of our business, in particular for Suprax. Texas was a very large state for the organization. We haven't really quantified how much of our business we do in Texas alone, but it was important for us to really put this lawsuit behind us.

Anubhav Aggarwal: Okay. So now this is fully provided for, and no more surprises can come here.

Vinita Gupta: That's right.

Anubhav Aggarwal: And on Levo, can you also talk about the competitive dynamics, let's say, now the number of players in the market, lets say over the next 12 months, how are you expecting these? How many players or new generics are you expecting in Levo market?

Vinita Gupta: It's hard to tell which of the new players can ramp up their capacity. But as we look at the positioning of companies, we are one of two. Mylan and us, are the only 2 that are equivalent to

all 3 RLDs, which is critical to really gain substantial share. We think that puts us in a very good position.

Anubhav Aggarwal: Absolutely. So no doubt about Lupin's ability to get good market share now, I was more worried only from a price discounting perspective. We have more number of guys come in, that's why we expected that initially, 2 quarters back, you mentioned like you are expecting about 1 or 2 more guys to come in over next 1-year period, that's why I was just taking update over there, that's it.

Vinita Gupta: We still believe that there maybe a couple of strong players in the next few years

Nilesh Gupta: The other good thing that we clearly see is, getting approval across the RLDs is important, and we obviously have a significant head start on the headcount. We have not heard about other approvals at this point of time. So, I think it gives us the natural window.

Alok Sonig: Given the high tonnage, it's a 6 billion units a year market, so the value as well as pricing is quite sticky, from our standpoint. We are also vertically integrated here with all the RLDs, so just from a quality of being competitive in the space, we rate our ability to be robust. And we are working, obviously, with anchor strategies with customers so that we are able to create more stickiness in this product.

Anubhav Aggarwal: Just one clarity on this. When Lupin launched this product over last couple of quarters, did we normally come as a normal generic, like, when a new generic comes in, the price erosion is about 15%-20%. Given the dynamics in this market, we hear about some shortage of the Levothyroxine, very high-volume product. So was this a special case where the price erosion was less than typical, or this was a typical entry of Lupin?

Alok Sonig: The price erosion in general, I would say, without giving specifics, it's a bit less than your traditional generic. So that's the basis of the comment I made earlier, that it is sticky from a value standpoint. Yes, and large volumes, so you have to be sufficiently invested in this product to make a dent in the marketplace.

Moderator: Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: On Levothyroxine, we now have RLDs for both Synthroid and Unithroid. Is that correct understanding?

Alok Sonig: Synthroid, Unithroid and Levoxyl, yes, 3 RLDs.

Nimish Mehta: And the other question on the domestic business. Again, wanted to know how much do you think is the impact of trade generics on our business? And in general, what do you think should be the outlook because of trade generics, basically in the industry?

Rajeev Sibal: As far as Lupin's business is concerned, we have only 5% contribution coming from trade generics, 95% is our branded generics. So, we do not see a problem as far as our branded business is concerned. And that's how we have been able to show growth, which is 12.8%, and always better than the market. Even in H1, we have grown at 12.5%. The strength of Lupin, as far as domestic business is concerned, is its portfolio because we are very strong in our chronic portfolio. Saliency of our chronic portfolio is 60% versus acute of 40%. Whereas in the market, it is other way around. Because of our saliency in chronic portfolio, we are absolutely in a good position to grow better than the market and that's what we are registering.

Nimish Mehta: Are we not seeing any impact on the branded business because of other company's trade generic business, that's what I'm trying to know?

Rajeev Sibal: Not to that extent. Let's say value wise, I think it's still very less and its more volume wise, but value-wise, ~95% is branded business for us and overall it is ~90% branded business for the industry as well.

Nimish Mehta: A few quarters back, we were talking about input cost increasing because of raw material cost increasing, especially because of the situation in China. So just wanted to know, are we now through that or are we still seeing some impact of that?

Nilesh Gupta: Those increases stuck for the most part. I think they've come down on the antibiotics side, but other than that, those increases stuck. They've become part of the new reality.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Nilesh, If you could help us, give us some update on the FDA status across facilities. And I mean are we on track to close at least one as you last mentioned by this financial year?

Nilesh Gupta: Obviously, we're not happy with our track record. We have 4 sites that have an OAI status, 3 of those have a warning letter, and obviously it's impacting new approvals from those sites. We have had another half dozen inspections which have been positive. But these are big meaningful sites where we have these issues. On the Lupin side, we are just doing a much deeper exercise. We talked in another forum on Quality First. It is a deeper project that we are doing, starting at our Pithampur site but extending to all sites, certainly all the OAI sites as well. The idea is to do a much deeper quality transformation. It works on everything, from people, products, processes, practices, everything. And the answer is that in the first calendar quarter, we would expect to put 2 sites up to FDA for reinspection, and then whenever the FDA comes and follows the process.

I think on Pithampur and Mandideep in particular, we'd like to take another quarter at least of deeper work before we put that up for reinspection.

Prakash Agarwal: And secondly, how do we look at our Japan business going ahead? I mean structurally speaking, we've been seeing price cuts every year now and margins are also lower than the company average. So how do we think about the business?

Nilesh Gupta: In fact, we had a price cut in October and we're going to have another one at end of the financial year. So, this year, it's going to hit us twice. But first of all, the EBITDA margin is pretty much equivalent to the company average. As you know, Japan is obviously going through a pressure, and the intent is to optimize on cost. We've done a lot of that. It has involved manufacturing from India, certain cuts on the manpower count as well; we've done those. We as an entity, are well positioned to ride out the storm. But, there are pressures in the market going forward. But as the #5 generic entity there, it's in a pretty solid position to be able to tackle those. From our perspective, the U.S. generics, executing the story on complex generics, executing on specialty, India that shapes the narrative especially from a growth perspective.

Prakash Agarwal: Understood. What I'm trying to understand, would it remain your third important market in the next few years? Or you would at some point want to concentrate more on U.S. and India?

Nilesh Gupta: The focus remains on U.S. and India. Japan has always been running on its own. It has been supported by India, of course, but the focus remains on U.S. and India. We will see what happens long term.

Prakash Agarwal: Got it. And last question on the biosimilar portfolio, if there's any update on the Enbrel?

Nilesh Gupta: It has been going strong. We had talked last time about a Q4 approval for Europe. We are still broadly on track with that. We talked about 2 clinical sites that they wanted to inspect, they have inspected one of the 2, the other one is still to be done. But broadly on track with that. End of Q4 approval and likely Q1 launch is what they're expecting for Europe. We already launched in Japan and through our partner, Nichi-Iko, we basically plan to launch later this month.

Prakash Agarwal: And for U.S.?

Nilesh Gupta: For U.S., the development is underway. As you know, the patent was upheld, and unless the appeal overturns it, it's out for a few years. Pegfilgrastim in the U.S. will be a more near-term opportunity. We are on track for filing next year, and I think that'll be a very nice opportunity for us.

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Vinita, on the U.S., when we look through this year, barring-in the scale-up in the Levo that's going to come through, what will be the other drivers for the business in the U.S. this year from this base onwards?

Vinita Gupta: The base business itself is strong at this point and Levo, of course, will be the largest revenue contributor from a ramp-up standpoint. The injectable products that we had hoped to launch, at least one by now got delayed by a month. But in the next quarter, we should really have 4 products in the market. We think that we probably will have another 5 to 7 potential launches before the end of the fiscal year. But the largest growth driver still will be Levo.

Nilesh Gupta: We also talked about a pretty solid base business. There is this US$ 170-$180 million business that we are building on. It's a nice platform to build on from here.

Alok Sonig: There is also an opportunity of relaunching some of the products from our U.S. site where there are some interesting opportunities. We will obviously share more with time. There are a couple of significant relaunch opportunities, given competitive disruption issues in supply. Those have become interesting for us. The injectable launches are eventually sizable. They're strategic in the context of this fiscal but as they ramp up in the next fiscal, they will become financially relevant as well, as Vinita was saying. But the rest of the business is holding up really well. We are seeing volume gains and as Levo ramps up, that's an exciting focus for us for balance of the year. We then get into approval and launch of generic ProAir and so on. That's the kind of the path for the next 6 to 12 months.

Nitin Agarwal: If I just extend that a little further, for FY '21, obviously, there is this big ProAir launch, which is lined up along with probably a lot more scale-up in Levo. What else should we really look forward to in the U.S. for next year?

Vinita Gupta: ProAir plus these Injectables, like Alok said. Levo for certain, with share ramp up given the new expanded capacity in place at the end of the fiscal year. We have been working hard on trying to accelerate growth on Solosec, also optimize our gross to net. We expect that to be a material contributor on the specialty front next year. Those will be the major products in the U.S. And then ex U.S., we should have Etanercept in Europe. We should have Fostair, which would be a material product in Europe we hope to launch next year.

Nitin Agarwal: And Vinita, on Enbrel, what is the competitive situation right now. The fact that we are going to be almost a year and a half behind your launches, how do you see that playing out for ourselves?

Vinita Gupta: As of now, we still think that we will be the third entrant. We don't see anyone else that is far along, and who can beat us. We still think that we should be one of three, so a pretty good position and a good opportunity.

Nitin Agarwal: And then just a couple of housekeeping questions. The other income is pretty large this quarter, is it largely Forex gains or there's something else to it?

Rajiv Pillai: Other income has got Forex gain as well as treasury income.

Nitin Agarwal: Okay. And lastly, we have talked a whole lot about the cost optimization efforts in the previous quarter. How much of it has begun to reflect into the numbers just yet?

Vinita Gupta: Some of it. We had mentioned that we will start seeing the impact to a small degree this year, a larger degree next year. First half of the year, we've had some impact, we'll have a larger impact in the second half of the year, but a material impact next fiscal year.

Moderator: Thank you. The next question is from the line of Damyanti Kerai from HSBC. Please go ahead.

Damyanti Kerai: I would like to understand the U.S. a bit better. So you mentioned in your opening remarks that the price erosion in the U.S. base portfolio is now down to single digit, and we have done some three launches during the quarter. But if I look at quarter-on-quarter performance for the U.S., I'm seeing around 15%-16% decline. So what has led to that?

Alok Sonig: As you know we had a limited exclusivity with Ranolazine. So, this is really the first quarter without any of that factored in, and that's really the biggest driver. As you go back to the third quarter last year, that would reflect base at that point in time and post that Ranolazine came along. This really reflects the first quarter without the Ranolazine and that explains the decline.

Vinita Gupta: Yes. Ex-Ranolazine, our base business grew quarter-on-quarter.

Damyanti Kerai: Okay. So the entire difference is due to the Ranolazine part, right?

Vinita Gupta: That's right.

Damyanti Kerai: Okay. Also, if you can update sort of key inhalers, which you're working on. So albuterol we are targeting for first half of next year. So what about other opportunities, the key ones?

Vinita Gupta: As mentioned, Fostair, which is a material opportunity for Europe, we expect to launch it in the second half of next fiscal year. That's already filed. We have multiple products in development, gSymbicort, gDulera, gFlovent, others. We have very rich pipeline on the inhalation front.

Damyanti Kerai: Okay. The Symbicort opportunity is coming only in FY '22, right, which we earlier indicated?

Vinita Gupta: We talked about Tiotropium, gSpiriva in 2022. We are first-to-file on gSpiriva and hope to be in the market in 2022. gSymbicort, I don't recall off the top of my head the launch date, but I think it's after gSpiriva.

Damyanti Kerai: Okay. And finally, how should we look at the tax rate for this year and next 2 years?

Sunil Makharia: Our effective tax rate is largely in the range of 25% to 30%. However, the tax rate worked out on a consolidated basis, looks high because of the lower denominator, given losses in some of the subsidiaries and no further DTA being created towards the same. For the purpose of your calculation, you can take the tax rate of about 45% for the full year.

Vinita Gupta: In the years to come, we have multiple initiatives underway to bring it down first to 40% and then into the 30s.

Moderator: Thank you. The next question is from the line of Shyam Srinivasan from Goldman Sachs. Please go ahead.

Shyam Srinivasan: The first one is on the regulatory environment, right? We could count about 15 warning letters for, like, India-based manufacturing plants, maybe Nilesh and Alok maybe just stepping back, not necessarily only Lupin, but what is happening? Why is this spike in terms of warning letters? I'm not using the word targeted to India, but I'm just saying, is there something that's changing, say, after the sartan issue last year and a series of popular press writing about this whole issue? Can you just walk us through what is happening there from your interactions with the FDA, has something changed? That is question one. And how are we, as management, responding to kind of give comfort back to the FDA?

Nilesh Gupta: One part was the sartan issue that led to certain warning letters, that is isolated to some companies that have had concerns around that area. I think investigation, in general, has been a broader industry issue. It's certainly an India issue as well, but I would say it's broader than that. A lot of the warning letters, including Lupin's, have reflected on aspects like that. From the FDA's perspective, their first priority is to ensure that what comes to the U.S. is safe, effective and that is really their approach. India supplies now close to 45% of what gets consumed in the U.S. in terms of generics. We will have the largest share of approvals. We will also have the largest share of issues. So certainly, there's a little bit of it is that. It's exacerbated by what you're seeing right now on the areas like investigations, issues like the sartan issue. But at the broader level, I think, India is very significant player. From our perspective, it is that broader level of assurance that FDA would expect. That's exactly what we talked a little while ago about working at that deeper level to ensure that it's not just investigation but everything else that happened as well. How is that in line? How is that compliant? So that year in, year out, you are able to assure compliance. That is really our goal. From our perspective, what we started as a program right now will be a multiyear project. But it'll really going to be an ongoing thing, at one level for us to continue over the years to ensure sustainability, quality and compliance.

Shyam Srinivasan: It is also getting talent from outside, like, I think you made an announcement on the quality side as well. So are people also part of the solution, new people coming in to bring a quality perspective?

Nilesh Gupta: If I was to flash 2 years back, our reliance would be much more on consultants to help shore up, and we felt that we needed to add to our capability. We've pretty much got the best capability that there exists in India, and that's why we looked globally to make sure that we get the right kind of person on board to lead our quality and compliance team. I'm very happy with bringing Johnny on board. I think he brings the right kind of expertise. Obviously, he is going to spend a lot of time in India because that's where the lion's share of our plant and manufacturing is. I think we have to strengthen people, but it's also about increasing bandwidth and that's really one of the things that we're focused on. But then some of the areas that we are focusing on like training, getting competencies, getting people ready for inspections, that is part of what is required to be done as well.

Shyam Srinivasan: Got it. And my second question just is on the press speculation around the Japanese divestment of the entire business. Can you just comment formally that it is part of a business, now it's 11% of sales before even the CritiCare got divested. So is there a capital allocation or a change in the way we think about some of the individual geographies that are at Lupin today?

Nilesh Gupta: We can't comment on speculation. That's exactly what we wrote to the stock exchange as well. In all of our businesses, we would look at options, alliances, what you may have. But there's nothing concrete to report at this point of time.

Vinita Gupta: And I'd say, we look at every geography from a self-sustenance standpoint, and get majority of the countries to be self-sustaining and work towards getting to the company's average level of EBITDA.

Moderator: Thank you. The next question is from the line of Kunal Dhamesha from SBI Capital. Please go ahead.

Kunal Dhamesha: I have two questions. First is how big is the new Levothyroxine capacity as compared to our currently ramped up capacity?

Nilesh Gupta: We have not commented on this in the past, but what we've said is it's a significant expansion from our current with the new plant. So actually, we end up with a multiple of the times of capacity that we currently have.

Kunal Dhamesha: And my second question is on the recent change in the Medicaid regulation, which kind of impacts some of the authorized generics. So do you believe that the recent change in regulations will impact the ProAir authorized generic strategy or albuterol authorized generic strategy as a whole?

Vinita Gupta: Yes, we don't expect it to have any material impact.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Nilesh, one question on the cost. You have been talking about cost control. Now if I look at this quarter, most of the cost items have grown ahead of your revenues. R&D is up 15%, employee cost is up 7%-8%. I am just wondering where we are because you mentioned it will come next year but we haven't seen any signs of cost control yet in the numbers.

Nilesh Gupta: You're right. I don't think you see it at a very quantifiable level right now. R&D, a little bit of it is lumpiness, typically we would expect Q2 to go up. We are trying hard with Alok and others to see if Q3 can be back to the Q1 kind of levels. It will certainly be at the Q2 kind of level, but we're pushing hard on some of the inhalation projects, for example. Obviously, there is an investment related to that. We talk about keeping that within 10% of spend, we will keep that. That in itself is not part of the purview of cost control. We have actually said that in the past because that's a growth driver, that's something that we will invest in. On the rest, like Vinita said, it started accruing, it is still small, it'll be more material in the second half. It'll be really material in the next fiscal year. We actually have improvement in some of these lines, but they get tucked with the reclassification of some expenses and stuff. So, employee cost ended up carrying something which should have gone into another line. There's a little bit of forex, which has cost us on some of these lines as well. It is small enough to get muddied right now, but in the next fiscal, it will be meaningful enough.

Vinita Gupta: The employee cost also had some of the incentive, increments for the past fiscal year that came into this quarter, that is effective from July.

Rajiv Pillai: On the reclassification, the normalized number that you look at, Saion, is around 825 versus 850, I would say it contains reclass to the extent of about INR 25 crores.

Saion Mukherjee: And just on R&D. I mean the point is that I know you're doing inhalers, biosimilars etc. which could be quite lumpy. But there are a lot of uncertainties that we deal with in each of these programs. You do not know how the market is going to shape up many years down the line. So how are you thinking about R&D? I mean is there a way to reduce risk? Or how are you thinking? I mean if I have to think like slightly longer term, do you think this number will go up? Go down? What is your assessment once you're done with these projects?

Nilesh Gupta: Saion, we actually took a really good, long hard look at R&D about 2 years ago. Basis that we recast some of that, in fact we cut down some of the areas like Drug Discovery at that point of time. We optimized spend on even biosimilars at that point of time. We offset costs through partnering with financial partners for some of it as well. We're well optimized in terms of the areas to spend. There is this lumpiness on the inhalation side, obviously that's one of the biggest spend that we are doing right now, and we have a pretty large inhalation pipeline right now, Vinita talked about it. As we get success, we'll likely only push even harder to get those products

done. We've always talked of keeping it under 10%. Obviously, once the sales move very meaningfully, if you span out 5 years later then obviously it comes down in that. But in the next couple of years, we basically would see it at 10 odd percent. Even in an absolute term, we talked about the fact that this year would be more or less in line with last year. We're still on track with that. Next year will be a slight increase, again, we talked about that, primarily driven by spend in areas like specialty. We're pretty comfortable with where we're holding the R&D line.

Vinita Gupta: We have a pretty balanced pipeline. It's not really too much in one direction or the other. And we have a very balanced pipeline of inhalation products or complex injectables, oral solids; there again, we see the opportunity of being exclusive or semi exclusive and biosimilars.

Saion Mukherjee: And you mentioned about launches this year in the U.S. Looking at next year, assuming there is delay in resolution, how should we think about launches for next year? And any meaningful launch that you can call out and highlight?

Alok Sonig: We are looking at about 15 to 20 launches next fiscal year. I won't be able to highlight or shine the light on any specific launch, but there are a few strategic and sizable launches next year as well. Of course, we will continue with our filing rate as we've shared earlier of 25 to 30 a year. This is normalizing for those plants as well, it is outside of those 2 plants that you mentioned.

Saion Mukherjee: And with your permission, just one last one on Solosec. Vinita, we are running at US$ 20 million or so run rate annualized and we talked about 150 -200. Now typically we see that in 3, 4 years, things start to peak out. So are you still confident of achieving that or you want to restate the guidance? And how exactly you are going to get the gross to net be the key driver or is there something else we can look forward to?

Vinita Gupta: We are still targeting the US$ 150 million, 15% share of the market. As we look at our current performance 18 months from launch, obviously we are not at the level that we had hoped to be. At the same time, we've seen in the last couple of years, companies have launched products and got to the right trajectory in year 3, 4. Given the fact that we have 7 plus years of exclusivity on this product, we have a good runway and are completely committed in building the product to that 15% share that we have targeted. In terms of how we are going to get there, it is a combination of tactics right from leadership. I just mentioned that we brought on board a new leader to head that business, someone with very strong experience in women's health and managing Bayer's women's health business, very successfully turning around products in women's health. So that was very carefully chosen in terms of talent to meet our current requirement. We just saw at how we have done over the first year and a half, looked at, in the last couple of months, at the opportunity to optimize and improve and there was tremendous opportunity right from the standpoint of converting the high-volume writers. We found that our share of high-volume writers does not where it should be. Our share of call to high-volume, the reach, the frequency at the high-volume writers is not where it should be. There is scope to improve that. Gross to net, with the coupon that we brought into play end of last year in

November, we saw a big part of the business go to cash, which is problematic for us. We are rebalancing that. We changed our coupon from US$ 25 to US$ 45 in the last month and have worked hard to try to ensure that we don't lose any volume of scrips while we make the change. So far, it looks fairly decent and we are looking at other means and ways. Right now, the calls on targets and the prescriptions that we want to convert from is really a small percentage of the patients that are diagnosed with or have BV, 20 million women patients that are affected but only 4 million that are treated. We would like to really be able to, through our direct to consumer efforts, be able to get to the broader population, to be able to get more women to the physicians, and make sure that we get the right share of high-volume writers, make sure that we get the right adjudication of strong managed care coverage that we have to be able to optimize the gross to net. So those are some of the areas that we are working on.

Nilesh Gupta: We are not calling it a relaunch, but there's a lot of renewed energy in this. We're far from done with Solosec.

Vinita Gupta: Absolutely. It's a foundation for us on our specialty business for women's health business. We're very focused on ensuring that it's a solid foundation and building from there.

Moderator: Thank you. The next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Just wanted to have a sense on the kind of remediation expenses. How should one really look at from the current level? Though we have already been in the process of correcting and all that. So from here, how should one really look at? Any sense on that trend? Because this could be a kind of relevant cost element also.

Nilesh Gupta: First of all, it's not material. Year-on-year, there's probably a decline on that number. I think we probably spent more on it last year than we would this year. And the intent would be more and more to have our own strength and capability rather than leaning on the outside for remediation.

Surya Patra: Okay. So that means currently whatever that we are doing is largely about the consultation expense, but it's not any major kind of changes to the system or something like that. Is that correct, sir?

Nilesh Gupta: I talked about the fundamental revamp, and that revamp is internally driven. it is supported by the outside but it's internally driven. I'm talking about people, processes, training. All of those are the soft things, so there aren't big costs associated with that but there is a lot of effort associated. That's what we're focusing on at this point.

Vinita Gupta: There is no capital investment as such.

Surya Patra: Okay. And secondly, on the U.S. business front. So over a longer period of time, so how do you see, so do you want to have that anchor product to be driving the growth the way it has been for a couple of years. So similarly going ahead also, do you think that a few anchored products that would be driving the overall U.S. generic business or U.S. business?

Vinita Gupta: Not really. From the generic side of the business, we have a pretty strong portfolio. Our base business is very well diversified and right now, very stable as we look at it. As we look at our pipeline, we have a very strong pipeline. The investments that we have made in pipeline in the last many years have been to ensure that we have a strong, rich, diversified pipeline of products for the future. We call out and talk about material product but any given year, we are looking at 20-plus launches.

Alok Sonig: We have to keep investing in the base business as well. U.S. is the largest market in the world from a volume standpoint. And as Nilesh said earlier, India based companies to be at the 40%-45% shares, that requires to be relevant given that tonnage and the market, which requires systematic investments in pipeline, which we've been doing over the last many years. Investing in the base business, obviously creating the complex generics capability which we have created and that has resulted in many more filings across areas that Vinita mentioned over in inhalation, long-acting injectables, complex injectables, biosimilars and so forth. And that would obviously add to the relevance of the base business and together would create a business, which would be very exciting for us.

Surya Patra: Okay. And just one last question on the WTO related export subsidies. What is currently the buzz word. So what is the kind of export subsidy benefit that we should be currently getting? And how important or how critical is this if the verdict comes against us?

Rajiv Pillai: Clearly, we are an export-oriented business as far as the markets other than India are concerned. We do get export benefits in terms of MEIS, SEIS. India has lost a case in WTO, but I think Indian government will also come out with alternative remedies. We have 120-day period which is public news for all the entire industry, and I think India is going to appeal this in the court. So, we should wait and watch and not come to any conclusions on how this is going to play out.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Alok, when you talk about some meaningful launches in the U.S., Vinita you mentioned about 4 or 5 injectables and then a couple of relaunches from U.S. For these, what's a typical sales opportunity that you see a US $20 million to US $40 million more or less per product?

Alok Sonig: Per product maybe not quite that. These are sizable launches, so these are relevant to the other kind of launches. I won't guide you to a number on a per-product basis, because as I said, some have been just competitively disruptive kind of opportunities that are presented, so we are still

working on way through those. Some are going to be smaller than the number you quoted but definitely very interesting as you put them all together.

Sameer Baisiwala: Okay, great. And for Levo, given the large volume product that it is and which means per unit lower pricing. So what's the kind of a gross margin that you'll be making on Levo?

Alok Sonig: Yes, so it's a healthy margin, and obviously we cannot give you a number, but it is a sticky business and margin.

Sameer Baisiwala: Is it better than the company average? It's 65% plus?

Vinita Gupta: Yes, it is.

Sameer Baisiwala: And Vinita, can you share what's the size of the Fostair product opportunity in Europe?

Vinita Gupta: The brand does €700 million.

Sameer Baisiwala: And the competitive dynamics?

Vinita Gupta: We believe at this point, we are the first company to file the product. We are in litigation already and we think there maybe 1 or 2 other companies that are working on it, but we believe that we have a head start.

Sameer Baisiwala: And one final question. If I see your margins and I think the right way to look at it is by excluding the in-license income that you have made 140 crore plus. Then margins are definitely not 20% at EBITDA level, it's much lower, and to my mind, it's actually lower than any of the last 10 quarters. So is this the new margins and the new rebuild over it or what is the outlook over here?

Vinita Gupta: Actually, gross margins is 63% without it, and on average our margin has been at the 62% to 64% level. It's obviously 1 percentage point below 64%, but it's still at 63% level.

Nilesh Gupta: And in the broader sense, we did talk and were very clear about the fact that Q2 will not be as good as Q1 and then Q3 will be built from there, and that's exactly where we are going. Al of it keeps triangulating back to that 18%-20% kind of EBITDA margin that we should be able to do with the current kind of business that we have. Obviously as newer stuff starts rolling out, we can improve on it. But 18% - 20%, we still feel good about for the rest of the year as well.

Moderator: Thank you. The next question is from the line of Arjuma Begun from Coast Five Investments. Please go ahead.

Arjuma Begun: One question on Brovana. When can we expect the launch in the market?

Alok Sonig: We have filed, and we will look for an approval between the first 2 cycles with the agencies. So, we are looking at potentially end of next fiscal launch.

Moderator: Thank you. The next question is from the line of Mayank Hyanki from Axis MF. Please go ahead.

Mayank Hyanki: I have 2 questions. The first one is on EBITDA margin front. So this quarter if you leave out the licensing income, we have done an operating margin of about 14%. Now you've obviously headed towards normalized margin of roughly 18%-20%. From here on, if see the recovery in the business, it's going to be probably gradual given gradual ramp up in the U.S. business and the headwinds of Japanese business will continue. So what exactly is the road map from reaching from current 14% to 18% next quarter and next to next quarter because you said that's something that we can do in second half in absence of any large product in the U.S. which you get an approval for?

Rajiv Pillai: I think we can talk about how you come to that margin percentage, but currently, the normalized EBITDA is trending closer to 17%. Looking at the Levo ramp up etc., we believe with better margin mix we should be able to deliver better. We can talk about this as to how you have arrived at it, separately.

Nilesh Gupta: Levo ramp up, business ramp up in general, especially in the U.S. all of those will help. We're carrying the full cost of Solosec without the returns. As that picks up as well, all of those will expand our margins. I don't think it spans a very long horizon to stick to that 18% - 20%. We have higher R&D expenses at this point as well, that will normalize a little bit.

Mayank Hyanki: Secondly, Rajiv, you said on the export incentive part but if you could because export incentive is about INR 250 crores in last year's numbers, so almost 9% of EBITDA. And this directly flows through the EBITDA. So can you give us the MEIS export benefit, which you claimed last year because substantial amount of in case there is MEIS, it does not continue or something, then this might be a potential hit to most pharma companies, not just you.

Rajiv Pillai: Correct. I can share that separately with you offline, on that number.

Moderator: We take the next question from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Nilesh, on the U.S. side, what is the compliance status of the site currently in terms of when do we expect to be compliant again?

Nilesh Gupta: Somerset is one of the 2 sites that we're hoping to put up in the first calendar quarter for reinspection. We feel pretty good about some of the programs that the site has made. There's another couple of months of good work that we need to put in, before it's ready for reinspection.

Nitin Agarwal: I think earlier you alluded to some interesting opportunities, once the site becomes operational that's really contingent on that front, in terms of maybe relocating some of the production to the US.

Alok Sonig: No, we're talking about, existing products which we had approval from that site, where we have opportunities now, so we are ramping up. So that is not tied to the compliance status.

Vinita Gupta: Nevertheless, we want to clear the compliance status to be able to get new approvals.

Nitin Agarwal: Okay. And lastly Vinita, on the branded business in the U.S. barring Solosec, beyond Solosec rather, how are you looking at this business on a broader basis, 2-3-year basis?

Vinita Gupta: We intend to bring in other products into the portfolio. Right now, we have Antara as another second brand. Methergine and Suprax are genericized. But we don't detail Antara so that's really going to go generic in the next couple of years as well. The whole focus is on building the women's health portfolio. We are looking at multiple opportunities that we can bring sooner rather later to be able to grow the business and offset or spread the commercial expenditure.

Nitin Agarwal: And if I can ask the last one. On the emerging market business, I mean as a strategy, where is the emerging market piece across multiple countries really fit in? And which of these markets as a business are we more excited about?

Vinita Gupta: South Africa is substantial for us – 4th largest part of our business, growing very nicely. It's pretty self-sustaining and has strong EBITDA as well. Philippines is a very good size as well and doing pretty well. We recently got a new management and the business has turned around, particularly in this quarter, significant double-digit growth. Mexico, Brazil; Brazil in the first half of the year has actually recovered from all the challenges of last year with 30% plus growth. Mexico, doesn't have the same kind of growth opportunity in the ophthalmic market that we are present in, but again has very strong profitability. I think those are the major emerging markets that we are focused on.

Moderator: Thank you. We'll take the last question from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead.

Rahul Sharma: Just wanted to know what would be the scale of Kyowa CritiCare, which has been divested?

Rajiv Pillai: Sales of last year was about INR 365 crores, which is about 2% of the total consolidated turnover of the company.

Rahul Sharma: Okay. It was a loss-making entity?

Nilesh Gupta: It's pretty much flat. There are times that it made losses and times that it made single digit kind of profit. Obviously, we were not able to scale up this business, and like Rajiv said, not-strategic

to the rest of the Japanese business, not-core. Certainly, that kind of injectables did not render well to the rest of the business, which is why we decided to get out of it.

Rahul Sharma: And what is the amount which we received?

Nilesh Gupta: We've not talked about that in the past.

Rahul Sharma: Okay. And what is update on the Japanese Etanercept launch?

Nilesh Gupta: We launched in June through our partner, and I think very imminently, we should be launching with Nichi-Iko as well.

Rahul Sharma: Okay. Any market share update

Nilesh Gupta: It is very early to comment on that. I think next year it will start ramping up meaningfully.

Rahul Sharma: And what about on the Europe front for Etanercept?

Vinita Gupta: We are expecting approval end of this fiscal year, first quarter next fiscal year. So, hope to launch soon after. We think that it's going to be a material opportunity for us.

Nilesh Gupta: I think it's a very nice opportunity for us next year.

Moderator: Thank you very much. We'll take that as the last question. I would now like to hand the conference back to the management team for closing comments.

Kamal Sharma: Well, thank you for your questions, and I do hope you had meaningful discussions thereafter. Look forward to speaking with you again next quarter and wish you all the best in the meanwhile. Thank you.

Moderator: Thank you very much. On behalf of Lupin Limited, that concludes this conference. Thank you for joining us. Ladies and gentlemen, you may now disconnect your lines.