



“Lupin Limited Q2 FY18 Earnings Conference Call”

October 30, 2017



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Moderator: Ladies and gentlemen, good day and welcome to Lupin Limited Quarter 2 FY18 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 presentation concludes. In case 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 Dr. Kamal Sharma. Thank you and over to you.

Kamal Sharma: Good afternoon, friends. It's my pleasure to welcome you to this Q2 Earnings Call.

With me, I have Nilesh, Vinita, Ramesh, Arvind, Rajiv, Sunil and Naresh.

As you would have seen from the results, the performance in the quarter has been good. We have done better than last quarter on a sequential basis. The top-line has seen a growth of 2% and the bottom-line, interestingly, has seen an improvement of 27%, -- although there is a decline of 8% on the revenue line on the corresponding basis and a 31% decline on the on the profit, which is in line with what we had been indicating earlier that there is a pressure on business in the U.S., primarily on account of consolidation of the trade partners and price reductions. But what is heartening about Lupin is that we have shown a very good growth in other segments of our business. As you know, US of course is a major driver of our profit and growth because it is about 35%. But India, which is about 30% of our revenues, has shown a growth of 24%.

EMEA, again, has recorded a very good performance at about 22%-23%. APAC, likewise, has shown a growth of about 6% or so. So that's something very characteristic about Lupin that only in the market in US where there is a general sense of overall, kind of, I would say, headwinds in terms of business that we have been under pressure. Otherwise, in every other segment of our business, we have done very well. And also, I think what is interesting and what is noteworthy is that our operational efficiencies have been improving and there is a concerted effort to get them on track and even better. As you would notice from manufacturing expenses which have gone down and also from R&D investment that we have been calibrating, in no way we are sacrificing on any of our projects, but we have been calibrating our expenses and making sure that we do not exceed what we have intended to do.

Having said that, I think we continue to work on our strategy to implement a growth path on complex generics, biosimilars and specialty. You will hear a lot more from Vinita on our forays in specialty that we have been building on and we are committed to build it further.

With that, I will hand over the call to Ramesh to give you a financial pen picture for the business and then we will open the floor for Q&A. Thank you very much.

Ramesh Swaminathan: Thank you, Dr. Sharma. So friends, we heard Dr. Sharma speak about the fact that we did particularly well this particular quarter vis-à-vis in fact the previous quarter.



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To give more color on that, US declined by about 15% principally because of, pricing pressure and of course because of loss of exclusivity continuing on Glumetza and Fortamet. India did spectacularly well at 24.3%.

APAC is also growing at 6.1%. Philippines, growing at 44%. EMEA growing by 22.1% including South Africa growing at 29%. Germany is also growing at 13.4%.

Latin America vis-à-vis the previous quarter grew by 9.9%. But vis-à-vis previous year again Latin America is growing at 41.5%. Mexico a stupendous 66.2% and Brazil by 30.1%. vis-à-vis the previous year. We have done really well across various regions. EMEA grew by 17.1%, APAC grew by 15.2%. India vis-à-vis last year was 16.4%. But of course, the decline was principally in the US itself.

In terms of EBITDA margins, at the beginning of the year we talked about a range of about 21% to 23%. I'm very pleased to present that we were able to maintain about 23.9% for this particular quarter. So of course, we were aided by tailwinds in terms of FOREX and R&D spends itself were lower at 12.2% of sales. And then, as Nilesh promised, our R&D figure is going to be in the Rs 500 crores range on a quarterly run rate basis.

There are couple of things which are actually disconcerting, essentially the working capital. As you would have noticed, it has gone up during the course of this particular quarter. But we do know that we have taken active taken steps to bring it down and we would see results coming in Q3 and Q4.

Whilst I was speaking to some of you in the course of last couple of hours, you wanted to know more about what the guidance would be for the next two quarters. We believe that the sales have hit the bottom and we would do better in the next 2 quarters.

With that, I would like to open the floor for discussions.

Moderator: Thank you very much. Ladies and gentlemen, we will now begin the question and answer session. The first question is from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal: Sir first question on the U.S., the decline that we are seeing because of pricing pressure and some concentration. Just trying to understand way forward, we still see a Q-o-Q decline. When do you think we are going to arrest this given that we have 5 launches, 10 approvals? Do you think this is the bottom and from here we can at least start seeing some improvement Q-o-Q?

Vinita Gupta: So Prakash, we hope to. I mean, this particular quarter, we had one, the impact of the Metformin erosion that we talked about last quarter, that continued into Q2. And we also had the Claris One impact. That is the reason why the erosion level is a little bit higher. But on an annual basis, we still expect it to be in the high single digit.



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- Prakash Agarwal:** The erosion?
- Vinita Gupta:** Yes.
- Nilesh Gupta:** But we expect the number to pretty much bottom out around this number.
- Prakash Agarwal:** Okay. And this after taking account the acquisition that you made?
- Nilesh Gupta:** Yes.
- Prakash Agarwal:** And secondly, on the facilities side, if there is any update. You had said that nothing is pending. However, we have not seen any approvals from the Goa and Indore. So if you could highlight that as well?
- Nilesh Gupta:** We have been trying to push the FDA to get an answer as well and unfortunately, we really have no visibility into these processes. But I think typically I am seeing that the FDA seems to take 6 to 9 months to reach closure and hopefully in the next couple of months we should have answers for both Goa and Pithampur.
- Prakash Agarwal:** Perfect. Thanks. And lastly on the India business, just trying to understand this 16% Y-o-Y growth, so that is a very good growth. So what would have been the industry growth and would the Lilly partnership would have helped the growing that grow to at least a couple of basis points faster.
- Nilesh Gupta:** So I think the industry growth was single digit at best and obviously so part of it goes on the destocking which happened in the first quarter. But I think we need a little bit more credit than that. Lots of good stuff I think if you look at new product launches, we were ranked actually second in terms of value of new product launches that we did. In the top 25 companies, I think we are the fastest growing at this point of time. I think alliances like the Lilly ones are important, but the Cialis product obviously is a small product at this point. It's just launched. So overall, I think a good solid execution story as far as India is concerned.
- Prakash Agarwal:** So for the full year we still expect double digit growth?
- Nilesh Gupta:** So I think we have talked about 15% growth for Q3 and Q4, but with the disruption of Q1, I think we will still be growing in double digit, but will probably be somewhere between 12% to 15%.
- Moderator:** Thank you. We have the next question from the line of Saion Mukherjee from Nomura Securities. Please go ahead.



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- Saion Mukherjee:** Vinita, this \$34mn decline in the US Q-o-Q, can you just take us through like Fortamet, Glumetza and Minastrin and the rest of the business because it's quite steep? So if you can just give more color on that?
- Vinita Gupta:** So a good part of it was really the additional volume loss in Glumetza. Of course, we don't want to give product level break up. But like I mentioned, we also had price erosion out of the Claris One negotiation and that was across our baseline. And Minastrin lost exclusivity in the quarter as well, so we saw additional competition coming in to Minastrin. So we lost volume as well as share. So you really have to see the triple impact of the Metformin erosion, Minastrin new competitors as well as the baseline erosion because of Claris One.
- Saion Mukherjee:** Would it be fair that these product-specific losses that you had exclusivity was a bigger driver of this fall compared to, let's say, the channel consolidation and the loss in the base business?
- Nilesh Gupta:** Not really. Actually, if you look, it is almost equal across the entire portfolio including the Metformins.
- Saion Mukherjee:** Yes. I mean, I know you don't want to give product level details. But there has been a significant drop. The question is out of this \$204 million that we have, do we really have chunky sales and how much from these top 3 products? So if you can just give a rough percentage of sales that these 3, 4 products would contribute, that would really help us.
- Nilesh Gupta:** So there are other products that we have of this size. So I think these products are now probably at the level where you only see incremental erosion and we are starting to see that happen.
- Saion Mukherjee:** So you mean there would be limited erosion in Fortamet, Glumetza from the levels of Q2?
- Vinita Gupta:** We don't expect any new competition in Fortamet and Glumetza. Sun is still expected to get it at some point.
- Saion Mukherjee:** Okay. And my second question would be on margins. I mean, with all this headwind in the U.S., you still seem to have held on to the gross margin. Is there any dynamics there? Because it seems like most of these are related to pricing and \$30 million or so loss on pricing should have had significant impact on gross margins.
- Ramesh Swaminathan:** Yes, gross margins declined a bit. That's more because of the fact that whilst we lost out on the US sales, we're able to make up a bit of it in terms of the India sales going up. But as you recognize, India sales is not as profitable as America itself, and that's why you find, in fact, the gross margins to be down. But this is not to take credit away from, our endeavors on operational excellence in terms of buying at the right prices / procurement excellence and a host of other things and that's the reason why you'll find that EBITDA margins has actually held up at 23.9%.



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And we did give a guidance for the range for it being around 21%-23% and I will still put it there.

Saion Mukherjee: Okay. And in terms of cost, how much you think you can take out or control, I mean if you look at your overheads, R&D, etc. from the base that you have currently?

Ramesh Swaminathan: We are working on several projects with consultants and we have been reaping the benefits of that over time and we will continue to benefit over next few quarters as well.

Saion Mukherjee: Ramesh, can you share a number on around that?

Ramesh Swaminathan: So I guided around 21%-23%, and I'm staying there.

Moderator: Thank you. We have the next question from the line of Ashish Rathi from Darsh Capital. Please go ahead.

Ashish Rathi: Vinita, just on a Methergine, how is the scale up for it going on at this point in time, if you could throw some color on that?

Vinita Gupta: So it's between \$5 million to \$6 million a month depending on the stocking with our customers.

Ashish Rathi: Okay. And any competition do you expect on this?

Vinita Gupta: We don't know. It's the sole approved product in the market and we had heard of a couple of other competitors working on it. We know that the product is pretty complex to make given our experience. So it's hard to tell. We haven't heard of additional competition that is imminent.

Ashish Rathi: Okay. And secondly on Levothyroxine, can you confirm if Lupin has filed for all the 4 RLDs that are there? And what will be the launch time? Are we sticking with the financial yearend kind of guidance you had given earlier?

Nilesh Gupta: We had mentioned earlier that obviously when you file, you have to file with only one RLD and then you need to supplement that with the FDA post approval. So that is the process that we are following. I think we might try to launch it at the end of the fourth quarter. But I think this is going to be a good meaningful opportunity in the next financial year.

Ashish Rathi: What is the addressable size as of now for us when we launch?

Nilesh Gupta: We have not looked at it in that segmented way because obviously you would take the biggest product and do the generic against that. But there is part of the customers that look at it, look at the world that way, there are some of them that don't. So hard to look, I think we are going to try to get share at this point of time. But I think the real fill up will come when we have completed all the other RLDs as well.



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- Ashish Rathi:** And how much time will that take approximately?
- Nilesh Gupta:** So like I said, in the next financial year we expect to be good on the whole line-up.
- Ashish Rathi:** Understood. And lastly, bookkeeping question on what is the split between the branded and the generic piece for the US for the quarter?
- Nilesh Gupta:** 20 for brands, 184 for generics.
- Moderator:** Thank you. We have the next question from the line of the Anubhav Aggarwal from Credit Suisse.
- Anubhav Aggarwal:** One question for Ramesh. Ramesh, on the India sales growth, can you just clarify this quarter there was like numbers were net, earlier they were grossed up numbers. So excise duty was earlier taken as other expenses. So when you have reported year-on-year growth of 16% India business, is that like-to-like or growth is much higher on a gross basis?
- Ramesh Swaminathan:** Y-o-Y it is 20%.
- Anubhav Aggarwal:** Okay. So is that the reason why sequentially other expenses have gone down as well?
- Ramesh Swaminathan:** It is a net off because it's on a lower base. You could say that it is marginally shrank in, but it will not be too much really, how much really would it impact because overall sales itself is only about 28% of our total.
- Anubhav Aggarwal:** So just to clarify, India's growth reported 16%, but on a like-to-like basis would have been 20% growth, right?
- Ramesh Swaminathan:** Yes, that's what it is, absolutely.
- Anubhav Aggarwal:** And there is no FOREX benefit in the other expense, right?
- Ramesh Swaminathan:** No, nothing.
- Anubhav Aggarwal:** Now just 2-3 questions on the US business to Vinita. One is on Levothyroxine, how many competitors do you expect because this product everybody started working in close to March 2016 or March 2015 thereabouts. What is your sense, Vinita?
- Vinita Gupta:** I don't know how many competitors will make it to the market. You know that it is on the FDA's priority list bucket, so they are looking to get additional competitors approved for the product. We are assessing how, what kind of share we can get with our bio study against one RLD because the other 2 RLDs are going to lag. But as we have this dialog with customers, we are not hearing of additional competition coming in.



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- Anubhav Aggarwal:** And is it true like when we break this market up with Synthroid what I heard that AbbVie's franchise is so strong that the generics may struggle on Synthroid but may get market share on the other RLDs? Is that true or is that just a sense?
- Vinita Gupta:** I think companies, AbbVie has worked hard to retain share but the market dynamics have changed quite a bit in terms of pricing pressure and the peers are also looking to really get pricing down as much as possible. So I do think that additional generic competition will increase the share of generics.
- Anubhav Aggarwal:** Just one more question on the Econdisc impact, when do you think it will start impacting? Is the process already started now?
- Vinita Gupta:** No, some of the process has already started.. We have already had a streamlined pricing across our share on purchases from both. But, in the next 12 months we will know how they are going to roll out their bidding process.
- Anubhav Aggarwal:** But is our exposure meaningful when the streamlining of process started? Because I think it started only from October, right? So is our exposure meaningful that we get impacted now versus we get impacted let's say, not immediately, but after 6 months, something like that.
- Vinita Gupta:** Yes, not immediately.
- Anubhav Aggarwal:** And lastly, on Tiotropium, when do you expect the trial to get over?
- Vinita Gupta:** So we expect end of this fiscal year for the trial to get over.
- Moderator:** Thank you. We have the next question from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin Agarwal:** Nilesh on the R&D expenses, we said we not really cut back on any of the priority projects. So philosophically what has changed in R&D spends versus if you could probably have done with lower spend back earlier in the day? So, not for yourself, but in general what the company is doing which you're beginning to do differently now since the R&D expenses are a lot lower?
- Nilesh Gupta:** Hard for me to comment on the other companies. But as far as we are concerned, I think we've looked a little bit at the portfolio. We have looked at some of the products that would have been marginal at best and those are the ones that we have taken out of the pipeline. But we are going to filing a very solid number of ANDAs. We filed 10 ANDAs in the last quarter even. So, I think we are not compromising the number of products. I think what is happening over time is that the regular generic portfolio is starting to reach that steady state where we are seeing steady number of filings, there is steady amount of spend connected to that as well. Obviously, a little bit of the funding is kicking in for us such as Etanercept. So that is helping as well. And on the Novel



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Research front,, of course, we have scaled down specifically the discovery efforts. So that is cutting out part of the spend as well. So I think it's optimization at this point and probably for the next few quarters we see it at this level, which is why we said basically we will be around that 500 crores per quarter. But I don't think we are compromising any meaningful opportunity at this point.

Nitin Agarwal:

But I mean do they constrain you in terms of your efforts towards building a specialty footprint, which is essentially a critical imperative for you over the next, let us say 4-5 year period?

Nilesh Gupta:

So I think meaningful investment in specialty is not taken in this number, especially internal, because that is not what we are doing at this point of time. So as we do that, either we even have to think of some imaginative funding around some of that, which we can. But I think in the near term the specialty pipeline is coming more from acquisitions rather than internal build.

Vinita Gupta:

I would also add to it that some of the repurposing of the NCE spend is to be able to create room for specialty investments. As we look at Solosec, for example, we are going to spend money on additional indications that can help us expand the potential for the product. And likewise, we will take on development opportunity that makes sense as part of our specialty portfolio, and strategically we wanted to create room for specialty spend and have started optimizing our overall R&D spend and reducing the NCE spend.

Nitin Agarwal:

Thanks. And secondly on overall from a strategy perspective, given with the pressure that you are there in the US and I guess even in our opening commentary we did highlight our solid growth in the non U.S. export businesses. So is there internally some sort of a shift over or more focus that we are paying from a resource perspective on a non US export businesses?

Vinita Gupta:

No. So we are making sure that we resource all of our major markets very effectively. You have US, India and Japan –the 3 largest. But soon after that are South Africa, the fourth largest market, and then you have Brazil, Mexico, Philippines, all at the next level. Well, as you saw in this particular quarter, we have been able to grow the other regions a very strong double digit. We want to continue to deliver that kind of growth and are making sure that they are resourced well. I would say on the R&D front, while majority of our investments are geared towards the US market, the kind of investments that we are making in biosimilars, complex injectables, also some inhalation products, these are all platforms that we can leverage globally and we are trying to really figure out the best way to leverage them globally so that we can get more out of our R&D investment.

Moderator:

Thank you. We have the next question from the line of Richard Hornby from DLD Asset Management. Please go ahead.

Richard Hornby:

I just wanted to ask questions around Levothyroxine. For some reason in my head I thought it was March of next year you were sort of targeting it, but it seems like that maybe pushed back,



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so would like to hear your thoughts on that. And B, I want to see your thoughts on Lannett. I know that they have their contract, I'm not sure if you are aware, they have their contracts expiring with their supplier Jerome Stevens in 2018. And I am just wondering if you are aware of that and if there is something you are sort of thinking about?

Nilesh Gupta: I don't think there is any change in the timeline. We have had PAI as well and I think we are on track as far as approval is concerned. But in our minds, we were always very clear that we need to get the other RLDs done before we get meaningful share. We now feel that we could probably start the process a little earlier. But by the time we ramp up, get product done, that is where we are feeling it is going to be, if at all late Q4 or otherwise likely into Q1 and thereafter in the next fiscal. So no change in the overall Levothyroxine timeline.

Vinita Gupta: Yes, as far as the Lannett goes, we were aware that they had a long-term relationship with Jerome Stevens that was coming up for renewal. But didn't have any further intelligence on whether they had renewed the contracts or not.

Richard Hornby: You are aware their CEO has stepped down?

Vinita Gupta: Yes.

Moderator: Thank you. We have the next question from the line of Purvi Shah from Sharekhan Ltd. Please go ahead.

Purvi Shah: Can you please let us know apart from Goa and Pithampur, which are the other plants that have reported some 483 observations?

Nilesh Gupta: I think we pretty much have EIRs for everything else. So Aurangabad that we had observations, we have an EIR for. The other blocks in Indore which were inspected, we have EIRs for as well. So I think pretty much everything is good and ready.

Purvi Shah: So it is only Goa and Pithampur that has left with so far an EIR?

Nilesh Gupta: That's correct.

Purvi Shah: And if you could just give us the other income breakup, because it is substantially high this quarter.

Ramesh Swaminathan: It's basically because of treasury income and because of FOREX, the component of FOREX is sitting in this.

Purvi Shah: Sir, could you quantify the number please?

Ramesh Swaminathan: Treasury is about 30 crores overall.



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- Purvi Shah:** And sir, is it the run rate that one should expect excluding this or how is it going forward?
- Ramesh Swaminathan:** It really depends on how FOREX pans out, so we could expect it to be lower if FOREX stays at the current rate.
- Purvi Shah:** And the other thing was also on the tax rate front. Sir, if you could just help us guide what is the run rate that we should be looking for the next 2 years?
- Ramesh Swaminathan:** I think between 25% to 28%, it's a broad rate that you could expect.
- Moderator:** Thank you. We have the next question from the line of Anmol Ganjoo from JM financial. Please go ahead.
- Anmol Ganjoo:** Help on a couple of data points which you shared with us last quarter. Vinita, on the baseline growth ex of Glumetza and Fortamet, we were at 11% last quarter for the US business. How would that number look like for this quarter?
- Vinita Gupta:** Actually this quarter we have seen an erosion because, as I mentioned earlier, Claris One negotiation. We had a volume growth. However, we had price erosion that more than offset the volume growth.
- Anmol Ganjoo:** But your follow up commentary in the last quarter was that a big driver was the Somerset growth, which would be 23%. So has this dynamic which you spoke about been reflected as much in Somerset as in our legacy portfolio in Lupin?
- Vinita Gupta:** Yes, Somerset business has continued to grow. So if I look at all of the segments of the business, the Somerset business has continued to grow a strong double digit and our brand business year-on-year also has grown on a double digit basis.
- Anmol Ganjoo:** And my second question is for Ramesh. Ramesh, last quarter you quantified the impact of FOREX on the profitability to the tune of Rs.72 crores. What would the corresponding number be for this quarter?
- Ramesh Swaminathan:** It's about 42 crores for this quarter.
- Anmol Ganjoo:** And my last question is to Nilesh and it's basically a follow through. You spoke about cutting some slack on the R&D spend side and obviously refocusing initiatives. As you went about through this process, is there any theme emerging about some areas or technology platforms you think are quite some distance away from monetization or you would put pretty lower down the ladder as far as attractiveness quotient is concerned?
- Nilesh Gupta:** I think the theme is only to focus on complexity and to focus on the right set of products. And I think the more and more you will see that happening in our pipeline. So I think on the oral solids,



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the focus is clearly the exclusive First-to-Files and complicated products. Obviously products like controlled release and likes remain important. And the same applies even for Somerset when we look at controlled substances even. And then, of course, the platform. So inhalation is the lead platform followed by the complex injectables and in parallel to the biosimilars as well.

Vinita Gupta: We have taken out a number of backfill products from our pipeline where we saw potentially additional competition sooner rather than later. So the oral solid pipeline has been prune down to products that can yield a good return.

Moderator: Thank you. We have the next question from the line of Ritika Jalan from Narnolia Securities. Please go ahead.

Ritika Jalan: How do you see the margin and revenue growth in financial year 2018?

Ramesh Swaminathan: I would think it will actually improve form here. 2018-2019 is what you're speaking about? FY18?

Ritika Jalan: Yes.

Ramesh Swaminathan: We are indicating about 21%, 23% being the range for somewhere in between.

Ritika Jalan: Any color on the number of filings or launches in financial year '18?

Nilesh Gupta: So in terms of filings, I think it's going to be north of 30. Like I said, we've filed about 10.

Ritika Jalan: Yes. Are you on track on that?

Nilesh Gupta: We have filed 10, so we did that and yes, we are on track for 30 plus filings. On the approvals, it would be a similar number as well and probably somewhere between 20 to 30 launches in the US.

Ritika Jalan: And any FTF filing?

Nilesh Gupta: Yes. I think there are several in the pipeline.

Ritika Jalan: And any target of debt to equity ratio?

Kamal Sharma: 0.4 at the moment.

Ritika Jalan: For full financial year?



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- Ramesh Swaminathan:** Yes. I think in a general sense, we have a capacity to borrow a lot more. But having said that, in terms of risk profile that we are trying to maintain, it would go up even 2, if that's what the intention of this question is. In that sense, it is always calibrate aggression from our end.
- Ritika Jalan:** But any plan for debt repayment or any schedule like that?
- Ramesh Swaminathan:** We have cash accruals of close to about Rs 700 crores. We are looking at expanding on acquisitions and so on. So it's really a question of what is the variable to fructify during the course of the quarter itself.
- Ritika Jalan:** And my question is regarding the working capital. There has been corresponding increase in the working capital. So if you can just split, how much is because of GST and how much is because of US consolidation?
- Ramesh Swaminathan:** There are host of reasons. There has been a significant increase in overall receivables, but we are working towards bringing it down and even inventories, it has actually come down, but we would like to see it much lower. So you would see good outcomes perhaps in the next couple of quarters.
- Moderator:** Thank you. We have the next question from the line Sameer Baisiwala from Morgan Stanley. Please go ahead.
- Sameer Baisiwala:** Vinita, if I look at your U.S. business on a full-year basis, roughly \$1.2 billion last year and this year you're probably sort of annualizing this quarter at \$800, so about \$400 million knockout over 4 quarters. So if I back out \$100 million because of price erosion, you say double digit, so \$300 million is largely on account of Glumetza and Fortamet? Is that a fair assessment?
- Vinita Gupta:** That's a fair assessment.
- Ramesh Swaminathan:** But having said that, it's not as such going to rest around that \$800 million. It would be certainly higher than that. So to that extent, I think your overall estimate is certainly off the mark.
- Sameer Baisiwala:** Fair enough. I get it. - Q1 was 238, but okay. But broadly speaking this is rough math. Yes?
- Vinita Gupta:** Yes probably...
- Sameer Baisiwala:** That's fine. Vinita, also you mentioned that there could incremental competition to Glumetza, but Fortamet may be not. But Fortamet, I see couple of filings out there, Nostrum, Aurobindo. You don't expect them to come in?
- Vinita Gupta:** We don't expect them in the next couple of quarters. Aurobindo potentially in the future.



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- Sameer Baisiwala:** And on Levothyroxine, just a quick clarification. So the one RLD that you are going after should be the largest which should be Synthroid, right?
- Vinita Gupta:** Yes, it is the largest.
- Sameer Baisiwala:** And Vinita, because this drug has been off patent for many years, so what really is the key entry barrier for generics?
- Vinita Gupta:** You're talking about Levothyroxine?
- Sameer Baisiwala:** Yes, that's right.
- Nilesh Gupta:** I think it's pretty complicated and pretty large bio study, first of all, and obviously you need high potent facilities to do it as well. So there are a few barriers. You need to be very efficient in your manufacture as well because it is not that it will be fanciest priced product that there is out there also? This is obviously an old product in the market. So I think it's a combination of these three. So I think it's going to be a good steady product for us to add. It's not going to be the biggest, but I think it will be a good sized product.
- Vinita Gupta:** Also we are doing 3 bio studies, so we are doing 3 products literally and apart from all of these other barriers.
- Sameer Baisiwala:** And one final question, Vinita for you. How do you see the US market in terms of how long do you think manufactures can keep taking very high price cuts and not be reactive to it? And B, any thoughts on the new channels of distribution such as Amazon getting in?
- Vinita Gupta:** So what we are hearing from other manufactures also is that everyone is struggling with pricing pressure and margin pressures in the last couple of quarters and most companies are getting to the pain point, the US manufacturers sooner than the Indian manufacturers, just given the cost advantage. But we are hoping that we are really at that point where manufacturers can't really take any more cuts because it's going to impact their ability to manufacture product on a sustainable basis and can potentially cause supply disruptions. In terms of additional channels, Amazon coming into the pharmacy market and potentially becoming another major customer is a positive. With all the customer consolidation that has taken place, you have 90% of the market with the 3 biggest customers. So we think that it is a real positive for the generics industry to get an additional channel into the market.
- Sameer Baisiwala:** And just final, just to complete this point, Vinita. On the first one, at what point do you think there could be supply disruption because some larger players walk away and leave the market? And so is that 6 months, is that 2 years away, that inflection point?



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- Vinita Gupta:** I hope it is 6 months, Sameer. When we look at what all of our peers are saying about the challenges in the US, all of them are echoing the same challenges that we talk about. So we hope that 6 months is what it is. Right now with WBAD and Express Script being the last major consolidation, at least on the retail front, we hope that's the end.
- Moderator:** Thank you. We have the next question from the line of Shyam Srinivasan from Goldman Sachs. Please go ahead.
- Shyam Srinivasan:** Just one question on M&A strategy, you of course announced Symbiomix just recently. But just your thought process and this is just tying into the previous question around consolidation, Will Lupin be one of the key players in trying to ensue the opportunities that are there that you will look for further targets and is there any specific geographies other than the U.S. that you would probably be interested in?
- Vinita Gupta:** Strategically we are looking to build that specialty business through acquisitions. The generic side of the business we have a good amount of investments in place, both in terms of pipeline, in terms of facilities as well as capabilities that we have created to build the pipeline. And as you have seen, I mean we are investing into building complex generic pipeline that we expect to leverage across the major markets, certainly the US and Japan. So majority of our acquisition investment focus is to build the specialty side of the business in the US as well as Japan and Europe. And we look opportunistically at investment opportunities on the generic front, but we feel like we are very well set on the generic front with the capabilities that we have. And we believe, what is essential on a genetic front is to really evolve this complex generic pipeline as opposed to doubling down or getting larger with more volatile portfolio. So our focus is on the generic front is very much on building the complex generic pipeline.
- Shyam Srinivasan:** So if I look at your 0.4x debt to equity, is there something that you have in mind that you can take it up to a certain level in terms of what could be a potential acquisition target?
- Ramesh Swaminathan:** Instead of debt to equity ratio, I think it is more important to look at in terms of it being a function of our EBITDA. I think up to 2:1 is what we think is a safe level. But having said that, there is no holy grail associated with it, meaning that it could actually go up to 2.5, but over time it will actually come down again. So rather look at as a metric over a period of 3 years, if at all we get to that levels.
- Shyam Srinivasan:** I mean last just housekeeping, the IndAS change in terms of the reporting as well as the GST. Is there any impact on the margins that you disclose, the 24%? Would that be like lower in case you use the earlier kind of a thing?
- Ramesh Swaminathan:** Very marginal impact now, I think it would be more or less the same.



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Moderator: Thank you. We have the next question from the line of Damayanti Kerai from HSBC Securities. Please go ahead.

Damayanti Kerai: So you have repeatedly mentioned that in our complex generic pipeline, inhalers are one of most important areas. So can you please update the initiatives here? And also please share your thought on recent FDA guidelines for complex generic which include many inhalers also?

Vinita Gupta: So on the inhalers, we have made progress on multiple fronts; one we have filed and got approved for nasal sprays which is a simpler technology platform in inhalation. And on the MDI front, we have filed for Albuterol and have had an inspection from the FDA and expect that we should get approved for potential launch in fiscal year '20. We are on track with Spiriva. We expect to complete the Phase-III trial with Spiriva this fiscal year and file soon after and continue to work on other inhalation products. Our Advair development, we had additional studies that we needed to do. So that has taken us a little bit longer and then we have other MDI products that we are pursuing on the inhalation front. In terms of the guidance from the FDA, they have said that they are going to be very open to pre-filing meetings, mid-cycle reviews. So really more transparency, more communication around the inhalation products and we really welcome that; the industry welcomes that. But given that we have invested a lot on inhalation front, we expect to be at the forefront of engaging in a dialog with the FDA to try to get these products approved sooner rather than later.

Moderator: Thank you. We have the next question from the line of Alok Dalal from CLSA. Please go ahead.

Alok Dalal: Vinita, apart from Levothyroxine, which could be the major launches for FY19?

Vinita Gupta: We have Axiron later this year, in the next couple of months hopefully we will launch and that will have a full-year impact in fiscal year '19. Levothyroxine, of course. Ranexa would be another major one next year. There are 2 controlled substances that we have launched in the last month or so. Hydrocodone/APAP is a big one. We hope to see the full-year impact of the launch next year. So those would be the major ones.

Alok Dalal: And you received one approval for generic TOBI, Tobramycin, but it has not been launched yet. So what is the reason for not launching that still?

Vinita Gupta: Actually the approval came in first cycle. It came very quickly which was positive. But the challenge was that we were not ready to launch the product and it is contract manufactured. So we have a lead time with a contract manufacturer. It is slated for launch within this quarter.

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



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- Neha Manpuria:** I was just wondering on our margin guidance, how should we look at the additional spend that we would require with the branded launch on the women's health from the Symbiomix acquisition that we made? Is that part of our 21% to 23% margin because I assume that would start flowing in through from this quarter onwards?
- Ramesh Swaminathan:** In a general sense, we have taken into account the fact that there will be some spends on that. But we do hope that there will more savings coming in other endeavors, of course, and outside in other markets as well. So we would kind of cover up for that.
- Neha Manpuria:** So that's incorporated in our 21% to 23% margins in that case?
- Ramesh Swaminathan:** Yes, in a general sense.
- Neha Manpuria:** And how much would the spend be if I were to look at the setup the platform of some...
- Ramesh Swaminathan:** We will give product wise details. I would appreciate if there is no question.....
- Moderator:** Thank you. We have the next question from the line of Abhinav Ganeshan from Canara Bank Securities.
- Abhinav Ganeshan:** Just I wanted some highlight on the India business. Has the destocking effect now gone away? How is your outlook for the next couple of quarters?
- Nilesh Gupta:** So I think we expect to keep growing at 15% in the next 2 quarters on a year-on-year basis.
- Abhinav Ganeshan:** Further, I have just to squeeze in one more question. What would be the number for Levothyroxine annualized sales on MAT basis?
- Nilesh Gupta:** I think like Ramesh has said in the past, you would appreciate, we do not share product-wise numbers or even forecasts.
- Moderator:** Thank you. We have the next question from the line of Aditya Ahluwalia from Invesco. Please go ahead.
- Aditya Ahluwalia:** So just gathering from the call, is it fair to say that the U.S. revenues have bottomed out for us now?
- Ramesh Swaminathan:** In a general sense, yes.
- Aditya Ahluwalia:** And is the 21% to 23% guidance assuming further price erosion in the US?
- Ramesh Swaminathan:** We also expect price erosion to kind of peaked out and also we think normalized for the entire year, we still can expect single digit number.



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- Aditya Ahluwalia:** But there is news of more consolidation happening the US sales there?
- Ramesh Swaminathan:** In a sense, yes. We have seen Express Scripts, Econdisc is coming together and there could be some impact because of that. But we reckon all of this when we give the number.
- Moderator:** We have the next question from the line of Ashish Thavkar from Motilal Oswal AMC. Please go ahead.
- Ashish Thavkar:** Just a follow up to the earlier participant's question. The Claris One impact that we had recently, the Econdisc coming along with Express Scripts. So for FY18 we have been guiding for 21%-23% EBITDA margins. What kind of operating leverage you have for FY19? What kind of EBITDA margins are you targeting?
- Ramesh Swaminathan:** I think it will improve from here. So even Symbiomix is certainly getting large, so there would be of course some revenue growth because of that. And we do expect buoyancy in other markets also to continue. And of course, there are some products which would be launched next year. So it's going to be a factor of all of those.
- Ashish Thavkar:** But for the specialty pipeline, the additional investments in terms of M&As, it would be more reflective in FY19? In the sense they you would be going more aggressive in FY19 in terms of targeting M&As?
- Vinita Gupta:** Yes. We certainly want to build our specialty business sooner rather than later. So we are aggressively pursuing opportunities. As far as possible accretive opportunities, I mean now that we have a women's health focus and we will be expanding our women's health commercial infrastructure, additional products into the portfolio, obviously, will help from operating leverage standpoint. Likewise, on the CNS front, neurology front for Japan as well as Europe, we are in the lookout for CNS product that can be promoted by our sales force. So we will continue to look to build specialty sooner rather than later.
- Ashish Thavkar:** And on the biologics front, the Etanercept filing, what you are targeting earlier, all those things are like very much achievable? Like we were talking about Etanercept to be filed in FY18 in Japan, so...?
- Nilesh Gupta:** Yes, we are on track. I think end of this calendar year itself I think we should target Japan filing and end of the fiscal, the European filing.
- Moderator:** Thank you. We have the next question from the line of Abhishek Sharma from India Infoline. Please go ahead.
- Abhishek Sharma:** Just back on gAdvair. I wanted to understand what are your timeline to pivotal studies now and what is the timeline to filing there?



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- Vinita Gupta:** Yes. We are in the process of repeating our PK studies right now and subject to the outcome of that we should start clinical trials in the next 3 months or so. And it will be end of this fiscal year I would say that we potentially start the Phase-III study.
- Abhishek Sharma:** And just on that, Vinita, I wanted to understand, I mean what was the challenge which led to repeat of these studies?
- Vinita Gupta:** It was back-to-back variability and we wanted to get more comfortable with PK studies before we start the pivotal trail.
- Abhishek Sharma:** And one question on tax rate, it has dropped this quarter. Has it happened because of change in geographic mix and how does one look at that going forward?
- Ramesh Swaminathan:** You would appreciate this is despite the fact that the weighted reduction has come down from 200% to 150%. It is more because the fact that we also opened up new avenues in terms of tax free zones. We have Sikkim now functioning, Pithampur continues and we have Mihaan also opening up. So all of those have contributed a bit. To the extent that there is actually loss making in certain other geographies, in fact there will be an erosion. But net-net, I think we will still be in the range of 25% to 28%.
- Moderator:** Thank you. We have the next question from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead.
- Rahul Sharma:** Just wanted to know the timelines for Solosec. When are the timelines where we could see the launch and scale up happening?
- Vinita Gupta:** So the scale up we are working right now. We are in the process of the validation batches in the next few weeks and subject to successful validation, we will be planning to launch -- we have said mid-2018 - hopefully sooner if we can.
- Rahul Sharma:** And another thing just on the other expenses anything where it's come off quite a bit in this quarter, if I look at it on Q-o-Q basis also? So could you throw some light on it or is this a new run rate?
- Ramesh Swaminathan:** It is actually a function of two things. One is of course the FOREX and second is essentially the R&D expense. R&D expenses are down to 12.2% of sales, so it's impact, actually a part of this is covered out here.
- Rahul Sharma:** Is there a FOREX loss in it, FOREX gain in it or anything?
- Ramesh Swaminathan:** There is a loss in the previous quarter and there is none this quarter.
- Rahul Sharma:** This quarter there is nothing?



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- Ramesh Swaminathan:** Yes.
- Moderator:** Thank you. We have a follow-up question from the line of Saion Mukherjee from Nomura Securities.
- Saion Mukherjee:** Vinita, in response to one of the earlier questions about product launches, you didn't mention some of the products which you had mentioned earlier like Prevacid ODT, Coreg CR, Tamiflu, Lialda. Can you just throw some light on the timelines for these products?
- Vinita Gupta:** So, Tamiflu, certainly we are hoping that we can launch in Q4.
- Nilesh Gupta:** For Coreg CR we still have a CRL pending which we expect to respond in the next couple of months. So I think late next fiscal year is when we would expect to launch and the same as for Lialda as well.
- Saion Mukherjee:** And what about Prevacid ODT?
- Nilesh Gupta:** Same story. Again we have a pending CRL that we hope to respond in either this quarter or next quarter and then we would expect to launch next year.
- Saion Mukherjee:** On the inhalation products like ProAir, Vinita, you talked about FY20 launch. Is there any dialog you had with the FDA that gives you that confidence given that there are no approvals so far on this product?
- Vinita Gupta:** We have had communication from the FDA, we have had inspection of the site and product related inspection, so that that is what gives us the confidence.
- Saion Mukherjee:** So do you have a target action date for this? This was expected this quarter, right?
- Vinita Gupta:** It's middle of next year.
- Saion Mukherjee:** Okay. So you would receive a response letter only then?
- Vinita Gupta:** Right.
- Saion Mukherjee:** And just one last question on your strategy. You mentioned about having very selected opportunities to target, but still you are talking about 30 odd ANDA filings. So out of these 30 ANDAs, how many would you classify as possible limited competition or where the barriers are relatively higher?
- Nilesh Gupta:** So I would say a good part. So I think in the 30 odd ANDAs we would have probably 4 or 5 injectables, 4 or 5 derm products that we would file. And of the balance, a good part would be products which have limited competition or are exclusive.



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- Saion Mukherjee:** And Nilesh, on injectables, last time you mentioned that there were some PK studies on long-acting injectables that were supposed to start in the June-July period. Is there any update on that?
- Nilesh Gupta:** Yes, so we did the first-time-inhuman study and decided to repeat one particular study before we go for pivotal one.
- Moderator:** Ladies and gentlemen, that was the last question. I now hand the conference over to the management for their closing comments. Thank you and over to you.
- Kamal Sharma:** Thank you, friends. I hope you had answers to all your questions. We look forward to speaking with you next quarter again. In the meantime, we continue to work hard towards getting better efficiencies and better performance. Thank you very much and bye for now.
- Moderator:** Thank you very much. Ladies and gentlemen, on behalf of Lupin Limited, that concludes this conference. Thank you for joining us and you may now disconnect your lines.