



“Lupin Limited Q3FY16 Earnings Conference Call”

February 5, 2016



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Moderator: Good Day, Ladies and Gentlemen and Welcome to the Lupin Limited Q3FY16 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode. 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. In case any of you wishes to e-mail your questions during the course of this call please feel free to send an e-mail to jim@bay-cap.com. I now hand the conference over to Dr. D.B. Gupta – Chairman, Lupin Limited. Thank you and over to you, sir.

Dr. D.B. Gupta: Hello Friends! I Welcome You All to Lupin's Q3 Earnings Call.

People waiting to talk to you are Kamal, Nilesh, Sunil, Vinita, Ramesh, Alpesh and Rajiv, and this side sitting are Naresh, Shakti and I as chairman of the company.

As mentioned during our last call, the performance of the company has improved significantly; in the third quarter with the profit improving by 30% over Q2. I am confident that we will be able to improve the performance from here on, and would be back on track from Q4 onwards. In short, what I wanted to say that we are on an aggressive growth track now. We are grateful to you, for letting people know what we have done. We believe that Lupin has a very large unutilized potential which will be put to advantage.

I now hand over to Ramesh, our CFO, who will take you through the details of the performance for the quarter. Thank you, Ramesh.

Ramesh Swaminathan: Thank you, Chairman. Friends, last time around we promised that we would deliver good results and that is exactly what we have done this quarter. We said that Q3 would be better than Q2 and Q4 would potentially be better than Q3. How else would you describe a result where the stock price jumped by Rs.200 today? If you look at, the sales performance itself, it is particularly pleasing because the US, which is our biggest growth engine, went up by 20% and the second largest engine, Japan, grew by about 16% Q-o-Q. We would wait for Vinita to take us through the details.

Whilst speaking to the investor community during the course of the last couple of hours, people have been asking me about the "other income" quantum. It is indeed pretty large at Rs.200 crores, but I rush to tell you that this is something which we believe would sustain because a chunk of this comes from amounts that we have received in lieu of contracts. So in the normal course you would have seen this as part of the sales line itself, but this is coming to the other income line - to that extent we still believe it is sustainable.

The other aspect of our results which is extremely pleasing is our EBITDA margins. The last time that we met, people raise concerns about the fact that it had gone down to 22% levels and we said that we are working on it. We delivered, and it is currently at 28.1%, despite R&D being at the same levels as Q2. Again if you compare R&D with Q3 of last year, it is up by at



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least Rs.130 crores and that actually speaks volumes about our operation excellence endeavors and the quality of our overall business itself.

Friends, you would of course ask me questions about the effective tax rate also. That is about 35%. This is essentially coming in from the fact that we have transferred a lot of products out of India which have not been sold in markets that they have been transferred to, leading to unrealized profits on which tax has been paid. That said, it is something which will normalize and we believe that the overall tax rate for the year would be potentially about 30%, 31%.

We look forward to answering more questions from your end.

Moderator: Thank you very much, sir. Ladies and Gentlemen, we will now begin the Question-and-Answer Session. The first question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.

Nimish Mehta: My first question is obviously related to the US business. Can you just take us through as to how have you been able to clock such a high growth on a sequential basis? Also the fact that when I look at the gross margin I do not see any absolute increase in the material cost, which means a lot of it is also probably because of price increase in some of the products. So, if you can throw some light on that especially on the Fortamet pricing, that would be great.

Vinita Gupta: Nimish, the growth in the US business on a sequential basis 20% is on the back of both the Generic as well as the Brand business; Generic business grew 18%, Brand business 56%. Generic business growth was primarily out of our baseline products, the existing portfolio, with minimal contribution of new products although we did launch four products, of which Lo Fibra was a very nice size opportunity, but we will see a more of an impact of the product in Q4 in the next year. So, majority of the growth in the Generic side of the business has been out of the existing portfolio and really across our entire portfolio. Oral Cephalosporins grew because of the flu season of course, and the rest of our portfolio grew as well. In fact, we had a few products that did not grow, so it was very promising to see sequential growth in volume, revenues, in majority of our products between Q2 and Q3. On the Brand side of the business, as I mentioned, we grew 56% on the back of Suprax as well as Antara. Suprax franchise, I am very pleased again starting to contribute at a decent level to the organization and the growth in Suprax was in suspension, but also in the protected dosage forms in the Chewable product, as well as the Capsule dosage forms. So it was a combination of both Generic as well as the Brand side of the business, primarily our existing portfolio, portfolio optimization and getting as much as possible out of our existing product line.

Nimish Mehta: So Suprax should be now sustainable or is it because of some erratic flu season or anything of that sort, just to know exactly about the outlook of the product?



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Vinita Gupta: So we should continue to see a pretty stable level, at this level, flu season actually was pretty soft, and late. So, hopefully in the current quarter as well Suprax continues to generate this level of revenues, if not higher. Like I said, the majority of the growth is from the protected dosage forms, the Capsule as well as the Chewable product, so we hope to be able to sustain it.

Nimish Mehta: Any color on the Fortamet pricing, have we seen the realization of increased price and what is the outcome?

Vinita Gupta: I am not going to comment on pricing, but Fortamet has grown very nicely, both in terms of volume as well as overall revenue.

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

Prakash Agarwal: My question is on Gavis acquisition. Any update there? If you see the IMS numbers, practically it is still showing \$30 million quarterly run rate, which comes to about \$120 million and we had a better guidance for calendar 2015. So how Gavis is progressing and when should we expect the deal to close out?

Vinita Gupta: Prakash, we were hoping that to close it by last quarter, but it took a little bit longer with the FTC for Gavis to divest the product that we could not acquire from them, maybe had an overlap that is pretty close to being done at this point. So, we are hoping that this month we can get FTC clearance and close the transaction. So, hope to have some contribution in the quarter at least a month out of Gavis, but definitely we will be able to contribute into the next fiscal year. In terms of revenue from the business, you are right on at \$120 million. They have had multiple approvals, they have not launched a part of the product that they have got approvals for. We are looking forward to launch them as soon as we acquire the business. We continue to be very optimistic about growth prospects of Gavis portfolio. The baseline portfolio, we think there are some synergies based on our relationships, the customers where we are strong as well as the products that they have approval for, and the new products that they expect to receive approval for the next fiscal year.

Prakash Agarwal: But just a clarification here in terms of getting approvals and waiting for the launches, does the Generic market wait for? How we think about it because the others would launch and eat up the pie?

Vinita Gupta: The companies have different philosophies and they are smaller organizations relatively speaking. They do not do launches at risk, as an organization compared to us. Some of the products they thought and we agree that if Lupin launches it, we would be able to garner better share as opposed to Gavis launching them and building upon it. So, a number of products they have not launched because of their own risk tolerance and we are looking forward to launching



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the product that they have got approval for. They have got a number of controlled substances, Methylphenidate, that fits very nicely into our plans for next year as well as other controlled substances, a couple of dermatology products that we hope to launch next year.

Prakash Agarwal: Second question is on Glumetza. How are we seeing as the traction since the market also has shown IMS numbers \$440-480 million, how should we look at the product in terms of rebating and discounting, because last time I remember you quoting about \$250 million as the market?

Vinita Gupta: So the product has held, the prescriptions starting this new year we have to wait and see what happens to the prescription level of the product as the new plans going to effect in January. But the prescription trend is looking pretty good and we have been able to access all of the major channels, all of the major customers, was a very successful launch for the organization, we have a close generic on the market. So we hope that it will contribute very nicely into Q4 and next fiscal year.

Prakash Agarwal: Last question on the India business. Shakti, just one clarification on how the WPI, which is negative currently and I believe the government ask us to link our portfolio India pharma at large, to WPI. So, as of now nine months it is negative. So once we reach and start fiscal 2017, as India pharma again, and as a corporate body, we have to link these prices downwards, what is the current thought there?

Shakti Chakraborty: Yes, I think there is a possibility, what you are saying is right. But, there are representations also to the government, but I think there is a downside for the entire industry.

Prakash Agarwal: They do not plan to shift to the CPI, because RBI in fact have shifted to CPI?

Shakti Chakraborty: I do not think so.

Nilesh Gupta: I think the act is pretty clear. That being said of course people are getting representation. So we will wait and see.

Prakash Agarwal: MR strength and NLEM impact?

Shakti Chakraborty: I think the NLEM impact we are yet to see what exactly is going to be like. Number of MRs we have got as of now about 4,800. We have planned of course to expand the field force.

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

Anubhav Agarwal: Ramesh, sir, you said other operating income is sustainable, but can you give split of other operating income and how much is export incentive there and how much is the other number?



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- Ramesh Swaminathan:** So, large chunk of it is actually export incentives, which will continue, for sure, and the other portion, which is coming in here in the normal course not have come in here, would come into the sales line, to the extent both are sustainable.
- Anubhav Agarwal:** So, would you say the other export incentives will be more than Rs.100 crores number out of this?
- Ramesh Swaminathan:** I would say, yes, for sure.
- Anubhav Agarwal:** I know export incentives will increase for everyone, but for us the total other operating income number has substantially increased of course Y-o-Y versus 1Q as well?
- Ramesh Swaminathan:** Last year, the incentives were not on the same scale, it has increased laterally only during the course of this year. So that is the difference. But if we talk about Q-o-Q, it is more or less in line except for the fact that we have this tranche coming in.
- Anubhav Agarwal:** If I were to roughly understand it, you would be getting roughly about 4% to 5% on export sales as export incentives?
- Ramesh Swaminathan:** We cannot take and compute it that way.
- Vinita Gupta:** The other thing to clarify is this tranche that came in, in lieu of contracted business. That is one time versus over business that we would have seen over a period of time over the year. So you need to really factor in that as well. Yes, so the export incentives is really the sustainable part of it Rs.100 crores plus.
- Anubhav Agarwal:** Vinita ma'am, if I look at the US sales over nine months that we have done in this year, roughly how much would have been the contribution on new launches, roughly would it be less than 5%?
- Vinita Gupta:** Yes, less than 5%, it is a very small contribution from new launches, majority of the growth has come from our existing portfolio.
- Anubhav Agarwal:** But if you look at the total approvals that we got, we got very strong number of approvals, none of them or very few maybe very large products, but in number there have been like almost, if I am not wrong, about 20 approvals that we may have got YTD?
- Vinita Gupta:** That is right, 22 approvals. We launched 12 products, but really the material for us that we launched was LoFibra and the Cefixime generic, which we had hoped not to launch actually, and now of course Glumetza into Q4, but until Q3, even LoFibra was at the end of Q3, so you see the impact of it really in Q4 and going forward.



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- Anubhav Agarwal:** Is there any specific reason for launching less number of products, or it is just the timing impact of the approvals that those which are surprises to the company?
- Vinita Gupta:** Some of them are surprises, we started receiving 15-month approvals which is very encouraging, obviously, and the pace of approval has improved as well as the speed at which they are approving drugs at this point. So, we have had one or two products where the approvals came sooner than we had anticipated, but majority of them are, the reason that we do not have them launched is because of patent hurdles, so the tentative approvals, rather than final approvals.
- Ramesh Swaminathan:** Some like the OCs that kind of backfill in that sense, so that you kind of need to wait for the market to open up as well, we will actually start shipping product out.
- Anubhav Agarwal:** Last question on Glumetza. After you have launched I think the innovator started cutting generic prices already?
- Vinita Gupta:** No, not as of yet.
- Anubhav Agarwal:** But with Express Script blocking the innovator has other PBMs done that as well, I am just trying to understand that can we end up getting more than 50%, 60% market share on this product, because of what PBMs are doing now?
- Vinita Gupta:** We are the sole generic on the market. So the relationships that we were aware of that Valeant had struck was primarily with Walgreens, and Walgreens is our customer for Glumetza. So we believe we should have the lion share of the market.
- Moderator:** Thank you. The next question is from the line of Girish Bakhru from HSBC Securities. Please go ahead.
- Girish Bakhru:** Just following up on new launches, would you say Azithromycin or Potassium Chloride, were interesting products to launch?
- Vinita Gupta:** Yes, they will be. The suspension is a material launch compared to the tablet and we are waiting to launch the suspension and Potassium Chloride will be a good launch.
- Girish Bakhru:** How big is the suspension market and if you could throw the competitive landscape what is it like that?
- Vinita Gupta:** I do not have that on the top of my head, maybe we can get back to you offline.
- Girish Bakhru:** Any update on Nexium?



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- Nilesh Gupta:** So, we have answered all the queries that FDA had in the meeting and we are following up.. Right now, we do not have visibility on when we will have it, we have product ready, and we are all set to launch the generic. So, my guess is obviously we will launch it next fiscal, but if we are lucky we will get it in Q4.
- Girish Bakhr:** On filings front, you have been maintaining 5 filings per quarter. If you could just give color on how many Derma filings have you done so far? For some of those products you did clinical trials as well on?
- Nilesh Gupta:** So, we have actually a good filings March ended last year, we will have close to 10 Derma filings in the whole year and we have done studies, we have done limited clinical trials, but we have not done any big clinical trial for Derma so far.
- Girish Bakhr:** Is there a regulation in place that clinical trials need to be done in US for Derma products?
- Nilesh Gupta:** No.
- Girish Bakhr:** Ramesh, the other expenses ex R&D still remain high. I think in the last call, we had mentioned some of the M&A related expenses should come down.
- Ramesh Swaminathan:** The expense in terms of the FOREX lines also, there is a loss which is actually going in there. Net of all the gains and losses that we make on the FOREX front, it is only about Rs.25 crores, but there are chunks of income and expenses sitting across various lines which we shared the picture somewhat.
- Girish Bakhr:** So do you think net of FOREX movement it is only Rs.25 crores increment?
- Ramesh Swaminathan:** Yes, I would say so.
- Girish Bakhr:** On working capital, is there any visibility on where this will ease out, particularly the...?
- Ramesh Swaminathan:** Operating working capital has gone up, it is more because of accounts receivable, but I should tell you that this is certainly being monitored at the highest levels, it will come down by end of the fiscal.
- Moderator:** Thank you. The next question is from the line of Surya Patra from PhillipCapital. Please go ahead.
- Surya Patra:** On the US business front, ma'am, can you just indicate what is the kind of Branded business this quarter that we have reported?
- Vinita Gupta:** \$15 million.



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- Surya Patra:** One important aspect is that after seeing a kind of a continuous price correction for our base portfolios in the last two quarters, on the third quarter, we are seeing kind of a superb sequential growth and a large part of that is again coming from the Generics only, which has grown 18%. So, is it kind of a significant volume growth that we have witnessed for our base portfolio or how is it or it is to a great extent contributed with a new portfolio?
- Vinita Gupta:** No, this is not a major contribution from new products, it is existing products, and a mix of both volume as well as price growth.
- Surya Patra:** So can we say, larger portion of the growth is led by the prices, because there was a kind of price correction for the base portfolio, suddenly we are seeing a kind of significant growth?
- Vinita Gupta:** No, like I mentioned it is a mix of both volume as well as price. In particular, all of that is just for the flu season, we saw a very nice volume growth, the rest of our portfolio grew as well, as I mentioned earlier, majority of the products in our portfolio grew.
- Surya Patra:** On the Fortamet prices front, I think that you have already indicated that twice the kind of a price hike that we have already taken for the Fortamet, but that has not been seen in the pharmacy prices. So can you just confirm on that front ma'am?
- Vinita Gupta:** I am not going to comment on pricing.
- Surya Patra:** Is there any kind of one-off gain apart from the FOREX gain of 25 crores that is there in any of the line item? That is the only item, right?
- Ramesh Swaminathan:** Absolutely.
- Surya Patra:** On Japan front, it is encouraging to see the kind of double-digit growth that we are seeing this quarter, so any visibility that you are providing for the subsequent period months?
- Nilesh Gupta:** That thing should continue at this stage, typically, Japan has grown at 10%, 15%, it will continue. There are some challenges, for example, for the next three years consecutively given **there have been Yakka cuts**, so, there are going to be price cuts, but we are also getting new approvals. So I think all in all, we cannot pretend end of the growth should continue.
- Surya Patra:** Whether in Irom we are seeing any kind of positive move there?
- Nilesh Gupta:** Yes, finally, but still small, it is moving in the right direction. But, I think we are still at least a few quarters away from meaningful improvements in Irom. It has got into that breakeven kind of level, a little bit of growth also, but I think at least another a few quarters before we have better story there.



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- Surya Patra:** This improvement in the gross margin what we are seeing sequentially, is it largely because of the product mix, while because our revenue contribution from India and US which are the key ones that has increased sequentially, is it the key reason for the improvement in the gross margin or something else?
- Ramesh Swaminathan:** Yes, it's largely that and of course there is a small bit coming in because the FOREX realizations itself if we talk about last quarter to this quarter, there has been a Re.1 depreciation of the rupee, so it has contributed a little.
- Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.
- Sameer Baisiwala:** Vinita, just a question on Fortamet. Would you say that the beneficial impact of price is really baked in for the full quarter or do you think the full quarter impact would be felt in 4Q?
- Vinita Gupta:** Full quarter would be felt in 4Q.
- Sameer Baisiwala:** There will be material difference between the two?
- Nilesh Gupta:** We told that there will be only little benefit in Q3, last time. So, let us wait for a quarter.
- Sameer Baisiwala:** Second question is on Glumetza. Is there a reason why you have chosen to give us a September MAT data of \$450 million?
- Nilesh Gupta:** For some reason that is probably the last that we had. No, we should have had January as well, but that is probably what we had.
- Vinita Gupta:** We probably have the January data.
- Sameer Baisiwala:** Yes, because that data is very different, the moment you shift from September to December?
- Vinita Gupta:** There should be, yes.
- Nilesh Gupta:** Yes, but we had no intention on that, at least is whatever our guide has.
- Vinita Gupta:** So, the fact is that the product, if you just annualized it, was probably at close to a \$1 billion level, but the thing we did not know and still do not know is to what extent the prescription levels will continue in Glumetza versus going to other products in the category and how many formularies are going to block it. So far it looks like majority of the channels have received the generic pretty well, but we are watching it very carefully over the next couple of weeks to determine what percentage of the prescription base one can expect to keep.



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- Sameer Baisiwala:** But there is one more data point which is a bit confusing that when Valeant reported in September quarter Glumteza sales of \$55 million. So how do we reconcile \$1 billion versus \$55 million if I annualize \$220?
- Vinita Gupta:** It is very hard to do that, but you can take the prescription level of Valiant last year and the price to determine what the market size could potentially be and then you have to assume that it will be blocked in some percentage of the market.
- Sameer Baisiwala:** When you have launched in the market., that is exactly what you are seeing in terms of size of the market?
- Vinita Gupta:** No, like I said, all of our customers, the channels have accepted the product well. We still do not know where at all it will be blocked.
- Sameer Baisiwala:** As you have mentioned earlier, the timelines for the approval for Sevelamer and Welchol which was end of fiscal'17, is there any change to that or do you think it would still take that much time?
- Shakti Chakraborty:** I think both the tablet products should be approved in the coming fiscal and both the suspension products will probably in the following fiscal. So Welchol, as of now, would be somewhere in H2 FY'17 launch, as would be Renagel.
- Sameer Baisiwala:** The tabs when you say next fiscal year, you are referring to first half, second half or...?
- Shakti Chakraborty:** For the Sevelamer tablet second half, it could even be last quarter, but that is what we are seeing at this point. We have seen this even in the last quarter, we have received FDA saying, we have been seeing them moving in a positive direction and then we get CRL. So I think FDA is also kind of figuring out these products better. May be that is one of the reasons why there are not approvals for these kind of products also
- Sameer Baisiwala:** But as we speak do you have an open CRL on this or have you responded?
- Shakti Chakraborty:** No, we do not have any open CRLs on either of the tablet products.
- Sameer Baisiwala:** But you do for suspension?
- Shakti Chakraborty:** We actually do for both the suspension products.
- Moderator:** Thank you. The next question is from the line of Anmol Ganjoo from JM Financial. Please go ahead.
- Anmol Ganjoo:** This is Anmol Ganjoo. A couple of questions; first for Ramesh. Ramesh, you pointed out that you cannot look at other operating income as a percentage of export sales, but when we look



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at it from FY'17 standpoint Rs.100 crores is the run rate which should be on account of export incentives, but on an annualized run rate, how should we be looking at this number?

Ramesh Swaminathan: It should be around Rs.400 crores.

Anmol Ganjoo: The other operating income or just the export incentives?

Ramesh Swaminathan: A little above Rs.400 crores all put together, I would say.

Anmol Ganjoo: Second question is on brands to Vinita. You spoke about 57% growth this quarter, but on a sustainable basis brands now contribute significantly less to our US sales and you had in the past spoken about restoring that mix, I know a part of that is a function of our superlative growth in Generic business, but where do we see this mix stabilizing in, and how should we be looking at organic growth of the brand business in the US and any inorganic would you might eventually mix?

Vinita Gupta: It is fair to say that we have made significant progress on the Generic front in the last year, both with existing portfolio, growing the existing portfolio, the pipeline that we have filed and then complementing it with the Gavis acquisition. We have our work cut out on the brand side of the business which we have not been able to build as effectively. What we have done so far is really optimize the brand portfolios and reorganize our sales force to get more out of our current portfolio and you are seeing the impact of that, but that will not take us too far because the Suprax entire franchise can give us only so much. So we are working on a couple of other initiatives, some organic and some inorganic that we hope to implement that will help us grow the Brand business. The organic moves we are looking at will hopefully show impact in the next fiscal year itself. But we have a lot more to do on the Brand business, there is no question about it.

Anmol Ganjoo: On Gavis \$120 million run rate now I am sure you would have had a chance to assess the pipeline at closer distance. So, when we look at this business from a 3-year perspective, what are the targets that you guys have set for yourself, I am not talking about FY'17 or FY'18, but how do you see the business shaping up and eventual contribution being in a more structurally in a 3-year timeframe?

Vinita Gupta: So, when we shared the Gavis potential, we did the transaction in the summer, we had mentioned that we expect to grow the business three times in the next two-three years and we believe now that we are closer to the business, we have been working towards integrating the business, have had a closer look into the pipeline and capabilities, we believe that we can do more than that. So, we certainly see the current portfolio as well as the pipeline contributing very nicely to our business over the next couple of years with a product that really complement our pipeline, good number of controlled substances, a good number of Dermatology products, GI products that complement ours. So, we are pretty excited, we have had six months that we



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waited to close the transaction with the FTC clearance that we need and we are as excited as not more, at this point.

Anmol Ganjoo: Would it be fair to say that there have been incremental positive surprise as you have had a chance to closely evaluate it?

Vinita Gupta: Yes.

Anmol Ganjoo: For Japan growth Nilesh you spoke about growth of 10% to 15%. This was a constant currency growth number, if I am right?

Nilesh Gupta: Yes, but I said probably 10% per year going forward, especially the price cuts are expected.

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

Saion Mukherjee: Vinita, actually I could not understand the Glumetza situation. If I look at prescriptions, they are down around 30%, 35% from the peak and the sales number has gone up. So, how should we exactly think about our potential market and how much we could make based on whatever initial assessment you have of the market?

Vinita Gupta: As I mentioned, it is hard to really predict what the baseline prescription will be. We should be able to see some leveling of the prescriptions now that the generic has come to market. So, there is a more affordable product on the market. The PBMs are certainly sending their message to the customers. So, we are monitoring it very closely and would really be able to tell I think in the next month or two, so by the end of March where this level is out, which formularies really block it, and which formularies encourage the use of the Generic.

Saion Mukherjee: It is a direct competition to Fortamet, right, something which you also sell? So, you think this competes well in terms of the product offering in terms of pricing?

Vinita Gupta: Yes, it got its own position actually, we found talking to customers, they see it having its own position and at least at this point we do not see one eating into the other.

Saion Mukherjee: On this Azithromycin Suspension, because we had this season which peaked last quarter, but we have not launched it despite the approval. Is it the reason for this delay?

Nilesh Gupta: Yes, we have had challenges with the commercialization. Thankfully, Gavis is very close to an approval on Azithromycin Suspension as well. So, we ideally see part of the commercialization happening from Gavis and the balance happening from India. So I think in the next month or two, hopefully we should be in the market.

Saion Mukherjee: So, you would launch it from Gavis initially?



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- Nilesh Gupta:** No, we launch part of the strengths, part of the pack from Gavis and the balance from Lupin India.
- Vinita Gupta:** So, the strength in between Lupin and Gavis complement each other.
- Saion Mukherjee:** Vinita, on the Respiratory programs for the US market, any update on that, what trials we have started if you can share that?
- Vinita Gupta:** Yes, so we have made significant progress; by December we filed our first nasal spray, we have continued development of Advair, Tiotropium and we have our first MDI, that is just going into the clinic right now and we have multiple products in development. So, a very significant progress on the Respiratory pipeline.
- Saion Mukherjee:** Vinita, when do you expect Advair to go to clinic?
- Vinita Gupta:** In the next middle of fiscal year.
- Moderator:** Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** Just on Perindopril in the past, we had a fine. What is the status there -- has that been paid or still litigated?
- Nilesh Gupta:** So, that is still through, that is going to be protected process, we are still going through the discovery process, example for court proceeding, we actually see it taking at least a couple of years before that matter will get resolved.
- Prakash Agarwal:** Secondly, if you could help us understand the staff cost. So while Q-on-Q it is flattish, I think last time we spoke because of the payout, bonuses and all, but this quarter also is there any significant change or additions we made in the staff side?
- Ramesh Swaminathan:** There have been increases on the R&D front, there have been increases on India Business front and there have been increases in terms of geographies, Brazil for example, has also come onto the scene. So, that is the reason why there has been some increase on the staff cost front.
- Nilesh Gupta:** So I think it also adheres with our increments, so the fact that the rupee is weaker when you translate it back into rupees that adds to it as well. So I think we have good number of addition in R&D, good number of addition in manufacturing and then several international positions as well.
- Prakash Agarwal:** If you could share the US FDA audit status into your key API and Formulations facilities?



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- Nilesh Gupta:** We have had, I think, literally a dozen audits in the last 12-months. Now, all our facilities have been inspected and for the most part we are fine I think probably 9 out of those 12 were without any reported 483s, obviously, we have been discussing the Goa matter, we are hoping to get a resolution on that soon. That being said in August, September, October, we have had an approval each in Goa. We have had a couple of audits in the last couple of months as well and those are being fine as well. I think for the most part we are fine. We are obviously waiting to close the Goa matter and hopefully that should happen soon.
- Prakash Agarwal:** So Goa is one among the three which received 483?
- Ramesh Swaminathan:** Yes.
- Prakash Agarwal:** The other two?
- Ramesh Swaminathan:** First of all, I do not think we shared this in the past, but I think we have had at Indore plant, we had at Aurangabad plant where we had three audits. . The Indore one has been closed already and I think Aurangabad will close hopefully soon as well. We are seeing a little bit of variability in terms of the amount of time, the FDA is taking to close EIRs, sometimes it is happening as little as one month, sometimes it is taking as much as six months to eight months, so hopefully we will close these matters soon.
- Prakash Agarwal:** What I understood right is, you already received approval from Goa, Indore and Aurangabad?
- Ramesh Swaminathan:** I think it had some 22 approvals and it has been scattered across all these plants.
- Moderator:** Thank you. The next question is from the line of Chirag Dagli from HDFC Mutual Fund. Please go ahead.
- Chirag Dagli:** On the Gavis acquisition, would we have to divest any products?
- Vinita Gupta:** Not we, but Gavis had to divest a couple of products before we could acquire them.
- Chirag Dagli:** But this is not part of the 60 ANDAs that we indicated as having acquired?
- Vinita Gupta:** No.
- Chirag Dagli:** When you say that the other operating income is sustainable, what you are indicating is this Rs.200 crores quarterly run rate is sustainable, is that what you are indicating sir?
- Ramesh Swaminathan:** A portion of that is something which will come into sales, because the portion that is the amounts in lieu of contracts, in the normal course should have been spread across a few quarters. So, it is sustainable to that extent that it would have been part of sales.



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- Vinita Gupta:** During the year. So, you cannot really assume Rs.200 crores per quarter.
- Chirag Dagli:** You cannot assume Rs.200 crores, but only the export incentive part is sustainable at Rs.100 crores, the other is something that we should assume, we should have spread...
- Nilesh Gupta:** Yes, I think there is other income, which keeps happening as well which comes into that line and somewhat the other one time that keeps happening pretty much every quarter, settlements for example come into that line as well. So I think anywhere from Rs.100 to Rs.150 crores is where the number would end up, not all of that being export incentives. What we were saying is that there were certain one-times in this particular quarter, we could have otherwise come into the revenue line.
- Moderator:** Thank you. The next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.
- Dheeresh Pathak:** I just want to follow up from the last question; up till last year, I think we were doing about Rs.120 crores export incentives for the full year, this year we are seeing it will be more than Rs.400 crores for the full year. Now what has changed in the government policies you could highlight that our export incentives...?
- Ramesh Swaminathan:** Essentially the government came out is in fact policy changes where they brought in something like MEIS and SEIS also, export incentives for both goods as well as for services. That is the reason why you find in fact a big ramp up on this particular line.
- Dheeresh Pathak:** Has the rate gone up by like 3x at which we were getting benefit?
- Ramesh Swaminathan:** The kind of products that have been included as well as the rate for sure.
- Dheeresh Pathak:** In your explanation, I think you referred to some sort of settlement income or something in the other operating income. Can you call that out as well?
- Nilesh Gupta:** I do not think this is possible for us to split it and share, but what I was saying was, there is some or the other settlement income which keeps coming up pretty much every quarter. So there would be always be a little bit of that in this line.
- Moderator:** Thank you. The next question is from the line of Purvi Shah from Sharekhan Limited. Please go ahead.
- Purvi Shah:** I had a question with regards to the US FDA thing that we have just stated that of the 12 audits, 9 was successful without any observation and 3 were where we had 483. If you could highlight on Goa? Also, the number of observations that we have received on the three plants?



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- Nilesh Gupta:** So like I said 9 out of the 12 audits were without any 483. We had 9 observations in Goa and 3 each in Indore and in Aurangabad; Indore, we have already had a close out, Aurangabad, we believe is going to be fine as well. Goa, we have answered all the issues that the FDA had raised, we believe that we addressed them to the FDA satisfaction, of course, we are chasing the FDA to see if they concur and do a close out on the EIR, that has still not happened, we followed up with the FDA and they said that it is still pending final review, so we are waiting for it to be closed. I also added that we have had 3 approvals from Goa thereafter, that, in addition to a lot more CBE30s and PASs that we access where the FDA often checks on the compliance status also.
- Purvi Shah:** If you could also help us in terms of the filings that we have had from these plants and any of the key filing that would be from Goa since there are 9 observations and since if we see the track records for the last 18-months the way FDA is moving?
- Nilesh Gupta:** Increasingly, a lot of our filings have been from our Indore plants, and now a lot of our new filings are happening from our Nagpur plant. So, in the last to three years you would see the filings are a lot more from Indore than from Goa, we have had some from Goa of course, and we have several products like Glumetza, for example, which we just commercialized, came from Goa. So obviously, Goa is important, but increasingly a lot of the new products are coming from other plants.
- Purvi Shah:** So, sir since you disclosed that Glumetza was from this plant, have we also applied or are we looking at another site from where we would like to supply this so that we could delist Glumetza...?
- Nilesh Gupta:** We do not see any risk in the Glumetza supply and as of now we have no plans to move it to another site.
- Moderator:** Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin Agarwal:** Vinita, my question is on the fact that we will have this exclusivity period for Glumetza over the next couple of quarters. Post that both Glumetza and Fortamet basically Metformin XR franchise would be a reasonably large proportion of a business and profitability. How do we see in terms of sustainability of the same and our ability to sort of protect that profitability from post 6-month period?
- Vinita Gupta:** Fortamet and Glumetza obviously have different competitive dynamics. Fortamet, we are right now one of two other than the AG on the market, Actavis has the AG. The only other approval that we have seen is from Mylan and they have not launched a generic as of yet. They have had approval for the last couple of years. Also, in the last couple of years, with Fortamet I think their patent was found valid. So, any new filer would have to certify and invalidate the patent



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which is already found valid, so it is more difficult to do that. So, we have a difficult PIV to do and we have not seen any other PIVs. So it is safe to say that the Fortamet franchise in the next couple of years, you could expect one of the competitors, but otherwise, it is going to be a limited competition product in the next couple of years. Glumetza is a different story. We have 6-months exclusivity on Glumetza after which I believe some has a tentative and there is another product filing I think it is Actavis again that has a filing. So, we would expect a couple of competitors. So it probably will be a 4 player market after the 6-month exclusivity is done, including the brand. The Brand Valeant has the deal with Walgreens. So, we would expect perhaps after the 6-months they will be competing as well.

- Nitin Agarwal:** On Glumetza right now there is no AG on that Valeant has come up with?
- Vinita Gupta:** No, we have AG free launch. So, we knew that the 6-months there would be no AG.
- Moderator:** Thank you. The next question is from the line of Abhishek Sharma from IIFL. Please go ahead.
- Abhishek Sharma:** On Gavis, I just wanted to understand the divestment which is required for this deal to go through. Has that happened already?
- Vinita Gupta:** Yes, they have come to an agreement with the third-party.
- Abhishek Sharma:** You are at a stage where you could basically take this back to FTC and ask for the deal approval?
- Vinita Gupta:** It is the FTC, they will be voting on it hopefully sometime in the next couple of weeks.
- Abhishek Sharma:** Vinita, I remember you saying earlier that one of the reasons which enthused you about Gavis was the manufacturing facility that you are getting with it. Given the fact that there is now this new thing about the government business where API from India and China would basically deem it, not as a product of US. So, would that have some sort of an impact on your estimate?
- Vinita Gupta:** No, we had not built in any of the government channel business in our forecast that we have given our expectation that we would be able to grow the business threefold was primarily based on their pipeline and really in terms of the impact of this news of the API supply into the government channel, we are still confirming what the real story is. Even if we are not able to supply API out of India, there are multiple other countries that can supply the US government. there are 70 countries on the approval list and I am pretty sure that most of Europe including the usual API suppliers out of Italy, Spain will be part of that list. So, I am sure we will have a lot of flexibility to participate in that business if not through our own API, through APIs out of other countries.
- Ramesh Swaminathan:** As I said, intents were always there in terms of it being another site for any eventuality and for controlled substances as well.



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- Vinita Gupta:** That is regardless, yes, addressing the government channel.
- Abhishek Sharma:** On the Dry Powder Inhalers that you are developing along with the Polish Company, where is that, because last time I heard you had mentioned that you are trying to scale up manufacturing. So, what is the status on that and has it got approved anywhere else apart from Poland?
- Vinita Gupta:** So, it is approved right now in Poland, it has been applied for in multiple other countries across all of Europe actually and they expect approval in Europe soon, in fact they have a relationship with Glenmark for Europe. We are pretty far along as I mentioned earlier we have a prototype together, we had certain issues on the IP front that we have resolved, they had to expand the facility, which they have already done. So they have invested into expanding their capacity, which is primarily for the US market. As I mentioned earlier that we expect to be in the clinic in the next fiscal year. So, we are making good progress on the product.
- Abhishek Sharma:** But given the fact that your facility is already scaled up, what else would hold you back from getting into clinic?
- Vinita Gupta:** We would do a pilot PK and then the pivotal PK. So we have done pilot PK and the product looked pretty good, we are in the midst of the pivotal PK right now, and after which we will commission the study, we already have the protocol agreed, we have all the sites identified, maybe even into the study, but we will wait for the pivotal PK results before we commission the study, it is the most expensive study that we will be conducting so far.
- Abhishek Sharma:** Are you taking the same device to US as they are basically taking to the other geographies?
- Vinita Gupta:** No, we modified the device for the US.
- Moderator:** Thank you. The next question is from the line of Nimish Mehta from Research Delta Advisors. Please go ahead.
- Nimish Mehta:** I just wanted some clarifications; you mentioned the Branded business about \$15 million, right, for this quarter?
- Vinita Gupta:** Yes.
- Nimish Mehta:** It has grown by 56% sequentially, so which was about \$9 million, \$10 million last quarter, is that a fair understanding?
- Vinita Gupta:** Yes.
- Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.



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- Sameer Baisiwala:** Ramesh, you were earlier planning to do Gavis either through asset buyout or equity, so have you decided on that and...?
- Ramesh Swaminathan:** It is actually a share buyout only, but the way that we treat it for taxation is different, so it would give us some tax breaks. So, it actually gives the effect of actually an asset purchase whilst it is actually a share purchase.
- Sameer Baisiwala:** Is it possible to quantify the tax benefit on this?
- Ramesh Swaminathan:** We do not wish to give it out, but it is fairly substantial.
- Sameer Baisiwala:** How do you get there?
- Nilesh Gupta:** Effective on a faster payback is going to happen based on what we are doing.
- Sameer Baisiwala:** But how do you get the benefit of the tax impact as the sales do ?
- Ramesh Swaminathan:** Section 338 election out there and the like, potentially because of that way the legal structure is structured out there in America.
- Vinita Gupta:** We can take it offline.
- Sameer Baisiwala:** Vinita, on Fortamet, I am a little surprised that since your price hike in September, what at least I can see on the IMS data that the prescriptions have picked up, so both for yourself and for the category is up maybe 5%, 6% Q-o-Q before and after the price hike. I would have thought it would probably come down. So what really explains this?
- Vinita Gupta:** The volume in the last couple of years if you look at it, the Fortamet volume has continued to grow, right now the growth rate has come down, but it still continues to grow. It is taking from the rest of the category from the other molecule, the Glitazones in particular.
- Sameer Baisiwala:** So, it just means that your price hikes has a very good chance to continue to stand?
- Vinita Gupta:** Hopefully.
- Moderator:** Thank you. The last question is from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.
- Anubhav Agarwal:** Just on Fortamet, if I see IMS, it shows a very high price difference between Lupin and Actavis whereas Lupin is very much sustaining its market share. Is it just that we see in the database these prices are so different, because there cannot be so difference that the other one is selling at half the price, is that realistic?



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- Vinita Gupta:** Yes, the database probably does not reflect the true pricing, we are fairly competitive.
- Anubhav Agarwal:** I have a couple of more questions; one is on the US market. How many target action dates if you were to look at over next 12-months you already have?
- Vinita Gupta:** We have got target action date on our entire pipeline with the exception of 6 products.
- Anubhav Agarwal:** That period for which you get target action dates is about 12-months?
- Nilesh Gupta:** No, in fact some of them are weirdly out much further also, very few though, but the most part most of them are usually 12-months. In a lot of these cases, those target action dates will likely be made for CRLs rather than approval.
- Vinita Gupta:** But we are starting to see 15 month approvals and so we are hoping that the FDA is looking and trying to do 90% of the products of that 15 months to review this application is strong they would approve it.
- Anubhav Agarwal:** South African market, what would be the market growth rate, because we have grown at 16.5%, we are among top five players in South Africa. My understanding was the market is growing only in low single digit in fact and we have been able to grow at 16%, 17% despite being top three, top four players. What is that you are doing so differently?
- Nilesh Gupta:** Yes, I think we have always outperformed the market as far as South Africa and that obviously reflects in increased market shares.
- Vinita Gupta:** Also, we have added other segments to our business, we have got into Institutional Injectable business, OTC business recently, so we have other growth drivers that we are adding to our business. Having said that, this past year has been a little bit of a challenge, our growth rate has been 9% in the nine months, otherwise we have been used to growing at 15% in South Africa. We are very confident of growing that business based on the strong foundation we have, strong team we have and the portfolio that we have put together.
- Moderator:** Thank you. I now hand the conference over to Dr. Sharma for his closing comments.
- Dr. Kamal K. Sharma:** Friends, as you heard our Chairman opening the call, and my colleagues on the table here. As we kind of promised last quarter, we made our journey in northwards now in terms of results of the company. I think we are very hopeful that going forward, we will be turning out even better performance, Q4 and next fiscal should see us doing even better than what we have so far been able to achieve. More importantly, I think the accent would be and looking at the profitability of the company. We slipped on our EBITDA journey and I think we are now back on it and hope to gravitate around 28% for the rest of the fiscal despite the fact that we will be spending more money in research, as you have heard Vinita and Nilesh speak that we are undertaking clinical trials, so even when you compare this Q3 with last Q3, there is increase



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in 3.2% in R&D expenditure and despite that the EBITDA margin is 28%. So thank you very much for your interest and look forward to speaking with you again with even more promising results. Thank you and bye for now.

Moderator:

Thank you very much, members of the management. Ladies and Gentlemen, on behalf of Lupin Limited, that concludes this conference call. Thank you for joining us and you may now disconnect your lines.