

## Operator

Ladies and gentlemen, good day, and welcome to the Lupin Limited Q3 FY 2014 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. Please note that this conference is being recorded. I now hand the conference over to Dr. DB Gupta, Chairman, Lupin Limited. Thank you and over to you, sir.

## Desh Bandhu Gupta

Hello, friends. I'm very happy to welcome you to this earnings call for the third quarter results. Joining me here are Nilesh, Vinod, Vinita, Ramesh, Alpesh, Rajiv was here – is coming, Rajiv Pillai, Sunil, Naresh. I'm really happy to inform you that for the first time Lupin crossed the turnover of INR 3,000 crores in a quarter with significant improvement in profitability. The major contribution comes to us from U.S., where the sales in this quarter was 45% of the total sales at \$215 million.

In another significant development, it gives me immense pleasure to inform you that we concluded the acquisition of Nanomi B.V. in the Netherlands. This is the first technology company that we have acquired, and it expands our technology capabilities into complex injectable space. I will now hand it over to Ramesh to give you further update on complete performance. Ramesh?

## Ramesh Swaminathan

Thank you, Chairman. Friends, as you've heard the Chairman speak, we're pretty happy about our performance, a lot of us, in fact the highest ever in terms of turnover, highest ever in terms of both EBITDA as well as in terms of profits. Growth on top line terms is about 21%. EBITDA margin is at 27%, but it could have been higher if the FX effect has taken out and you'd also appreciate that this is after taking into account an R&D spend of 9.1%.

In terms of business break up, API now constitutes 11%, but it has grown tremendously at 26% during this quarter. In terms of geographical spread, advanced markets now constitute 60% of the total turnover with U.S.A. indeed at 43%, Japan now still constitutes 15%, India is down to 23% of the turnover, but has bounced back in terms of growth.

Friends, so we're really happy with the results. We'd be happy to open the floor for discussions.

## Q&A

### Operator

Thank you. Ladies and gentlemen, we will now begin with the question-and-answer session. [ ] We have the first question from the line of Balaji Prasad from Barclays. Please go ahead.

**<Q - Balaji V. Prasad>**: Thank you. Hi. Good afternoon, everyone, and congratulations on the results. Firstly, on Nanomi, can you help us understand this acquisition better? I mean, the site says that they specialize in nano and microparticles. Firstly, am I correct in understanding that the principal areas of applications for these are cytotoxic are hormonal deliveries?

**<A - Vinita Gupta>**: So, Balaji, the company has got platform and capabilities in microsphere as well as nanoparticles.

**<Q - Balaji V. Prasad>**: Yeah.

**<A - Vinita Gupta>**: And has applications in complex injectables like depot injections...

**<Q - Balaji V. Prasad>**: Okay.

**<A - Vinita Gupta>**: ...as well as peptides. Also has applications in other areas like ophthalmics and respiratory, but our interest in the near term is to access some of the complex injectables that we are interested in through this technology.

**<Q - Balaji V. Prasad>**: Okay. So is it fair to understand that the technologies that you're getting now can be added on to some of the projects that you're working now or is it something going to be completely altogether different?

**<A - Vinita Gupta>**: We do not have much in terms of ongoing effort in complex injectables. We've been looking for partners for products that we are interested in. And so we are very pleased to be able to access a number of products that we are interested in this technology.

**<Q - Balaji V. Prasad>**: Okay. Another thing is that they say that they've been profitable since inception. Can you give more color on this, please?

**<A - Vinita Gupta>**: It's primarily an R&D company and so apart from developing the platform for complex generic injectables, they've been working with some of the big pharma companies to explore the application of the technology in other areas like ophthalmic and respiratory.**<Q - Balaji V. Prasad>**: Yes.**<A - Vinita Gupta>**: So that has kind of paid the bills for the company so far.**<Q - Balaji V. Prasad>**: Okay. Thanks. Lastly, can you give us a sense of the size of the acquisition?**<A - Vinita Gupta>**: Balaji, we hadn't announced the size.**<Q - Balaji V. Prasad>**: Okay. One final question on India and I'll get back into the queue. Where are you in your

discussions with the trade partners following the entire margin debate with the – on this.**<A - Nilesh Deshbandhu Gupta>**: So there's really no active discussion going on at this point of time. I think it's just the status quo that continues. The product flow is smooth. The disruption that we had in October is kind of behind us at this point. And I think it's pretty much the same for the rest of the industry as well.**<Q - Balaji V. Prasad>**: Thanks, Nilesh. So if I'm – to understand, you're saying that the product flow and everything is smooth and has resumed and that you've not given into the margin demands. Is that fair?

**<A - Nilesh Deshbandhu Gupta>**: Yeah. So I think we're still sticking with the demand that's laid down by the government.**<Q - Balaji V. Prasad>**: Okay. Wonderful. Thanks and all the best.

## Operator

Thank you. The next question is from the line of Prakash Agarwal from CIMB. Please go ahead.

**<Q - Prakash Agarwal>**: Yeah. Congrats on good set of numbers. Just wanted to understand SUPRAX numbers, \$24 million. I mean, is that a little slower than expected and which has resulted in lower gross margin, if you could explain that, please?

**<A - Vinita Gupta>**: So, Prakash, it's been a very soft season. As far as Q3 goes, the season has just started, just pick up in the last couple of weeks. So we have started to see momentum of the scripts on SUPRAX. So if you look at quarter-over-quarter compared to last year, there's been a decline in SUPRAX because of this seasonality, the lack thereof. But if you look at sequential quarters, Q2 versus Q3, we have seen a nice growth in SUPRAX, again, with the seasonality kicking in 28% growth in suspension and 26% in tablets.

**<Q - Prakash Agarwal>**: So would that be a key reason for a sequential decline in flat GPs?

**<A - Ramesh Swaminathan>**: Okay. Gross margin's actually declined a bit, in fact, as compared to the second quarter, principally because, in fact, there has been a ForEx impact. It's actually a translation swing of close to about INR 55 crores, which has come into the financials for this particular quarter.

Apart from that, there are other issues in terms of R&D costs being higher, which is actually principally led by in fact RM costs and so on. So these are some of these factors, but I think you should not look at it just on a standalone quarter basis. I think we should look at the full year for getting a more comprehensive view.

**<Q - Prakash Agarwal>**: Sure, sure. Got it. So INR 55 crores, should we add it back, right?

**<A - Ramesh Swaminathan>**: Yeah.

**<Q - Prakash Agarwal>**: On the ForEx account?

**<A - Ramesh Swaminathan>**: Yes.

**<Q - Prakash Agarwal>**: Okay. Got it.

**<A - Ramesh Swaminathan>**: On that score alone, that has – and also there are other – the overall ForEx loss in the financials is

close to about INR 60-odd crores, whilst on the gross margins line, there has been an impact of close to about INR 55 crores.

**<Q - Prakash Agarwal>**: Okay. Understood. But this, you normally hedge it – I mean, adjust it with revenues, so this INR 55 crores is with respect to the inventory?

**<A - Ramesh Swaminathan>**: No, that's true. That is in so far the hedge losses are concerned, but that was more or less the same as the last year. I'm talking about a swing because of in fact translation.

**<Q - Prakash Agarwal>**: Understood. Great. And just coming to Japan, I mean, good yen growth, I mean some growth coming back. So I mean, do we see – I mean, what has changed, A; and when is this yakka, which is the price – biennial price decline that comes in – that is coming to effect? And thirdly, some of the competitor, one of the competitor has moved out of the market from Japan. So I mean, is the market outlook changing, if management could give some color?

**<A - Ramesh Swaminathan>**: Yeah, as far as the Zydus exit is concerned, that is probably more to do with their own model and how they were performing rather than the market. As far as we are concerned in Kyowa, we see a full year growth of around 12%. The yakka announcements will come end of February and they'll become applicable in April 1. But partly, for Europe, the government has announced some long-term measures, which will include for new product introduction a 10% lower starting price.

So equally I think the next two years, there is large number of product going off patent, about INR 14 billion, INR 16 billion. And therefore – and also the government is yet to announce additional measures for impeding generic conversion. So overall, we think it should be a good – like three years, four years should be very good for us.

**<Q - Prakash Agarwal>**: Understood. And would you be happy with Irom's performance?

**<A - Ramesh Swaminathan>**: Irom is little underperforming at the moment, because as we explained last time, it's because of the contract manufacturing business, which has de-grown. But we have instituted a number of measures to get back on track. So we do expect that next year should be much better than – we should be back on track.

**<Q - Prakash Agarwal>**: Great. And last question before I get back to queue is on the tax rates. I mean, if you see the nine months and especially this quarter all these quarters are above 33%. So what is the – I mean, what is that we are looking for the year as a tax rate and for the next year, please?

**<A - Ramesh Swaminathan>**: Prakash, maybe we can assume the same rate of 33%, 34%. But during this year, as we've seen the impact of 2% on account of the dividend which we received from our subsidiary, so there is no impact on the PBT line, but the tax has [indiscernible] (11:57) almost INR 51 crores. So that has resulted into the – that has given the high taxes by almost 2%. But to be on the safer side, we can assume the rate of about 33% for the full year basis.

**<Q - Prakash Agarwal>**: Okay. Next year, please?

**<A - Ramesh Swaminathan>**: Around that. If we look at standalone India, we had tax rate be close to about 25%, 26%, but as you know, the minute you actually transfer product out of India, whilst the taxes captured the fact is it could be unrealized profits in America. So overall tax rates hover around 33%, 34% for that reason. And secondly, of course, the geographies that we are present in they're all high tax zones, 34% to 38% being the average.

**<Q - Prakash Agarwal>**: Okay. Great. I'll join back the queue.

## Operator

Thank you. The next question is from the line of Neha Manpuria from JPMorgan. Please go ahead.

**<Q - Neha Manpuria>**: Thanks for taking my question. First, on the R&D, we did about 9% in this quarter. How do we look at R&D as a percentage of sales on a full year basis going forward? Should we assume that 8.5%, 9% that we've been seeing?

**<A - Ramesh Swaminathan>**: Yeah, I think it's going to stay at that 8.5%, 9%. In fact, we're looking for some good revenue growth to make sure that we can live within that number going forward, because we're getting into more and more complex phases. We have injectables now. We have started dermatology, inhalation. All of that is going to add up, of course. The litigation is a part that we include in the R&D spend and that kind of stays pretty much at the same number also.

**<Q - Neha Manpuria>**: Okay. Got it. Second, on the two brands that we acquired earlier this year, how have their performance been? What is the response you're getting since last quarter was the first full quarter?

**<A - Vinita Gupta>**: We launched both really in the last quarter, Alinia as well as Locoid, and have seen some very encouraging response in the first couple of months, in particular for Alinia. I mean, it's off season. It's for diarrhea, so it's more the summer season that is – you see the incidence more. But nevertheless, we have started seeing scripts go up and have modest, but revenue contribution from Alinia on the brand business. And the Locoid promotion has also started to show results. We have seen the Locoid

prescriptions in the pediatrician segment go up. So both early days, but very encouraging results early on.

**<Q - Neha Manpuria>**: Okay. And my last question before I go back on the queue. If I look at our generic business, our base business, have we seen better than expected pricing? If I see across product baskets like it's being reported by the industry or we still continue to see price erosion versus historical trend.

**<A - Vinita Gupta>**: So, I mean, for the quarter per se, our base business has been very stable.

**<Q - Neha Manpuria>**: Okay.

**<A - Vinita Gupta>**: I mean, a good percentage of the growth has come from the new product launches, but base business itself has grown single digit as well, which has been very encouraging for us. And then depending on the competitive dynamics in the different products, some products have been down, others products have been up.

There have been products where with the reduction in the number of competitors, we have had the opportunity to take on additional business at better margin, better price. And we have seen some of that. And the others where we have seen price erosion as well, so but overall, the base business is very stable.

**<Q - Neha Manpuria>**: This is in line with the trends we've seen historically or has it been better than what we usually see, because we usually – I'm assuming we see a price erosion in the base business?

**<A - Vinita Gupta>**: Yeah. So it's been a little bit better than what we've seen in the historical trends.

**<Q - Neha Manpuria>**: Got it. Thanks so much, Vinita.

**<A - Vinita Gupta>**: Welcome.

## Operator

Thank you. The next question is from the line of Vivek Agarwal from ResearchDelta Advisors. Please go ahead.

**<Q - Nimish Mehta>**: Yeah. Hi. This is Nimish Mehta and thanks for taking my questions. Firstly, Ramesh, if you can just repeat the INR 55 crores ForEx impact that you mentioned, we missed out exactly what is it relating to?

**<A - Ramesh Swaminathan>**: It's actually related to translation impact of our closing balances in Japan. So it has actually gone and impacted our gross margins, because inventory is a part of raw materials consumed. So that's the portion that we are speaking about. So it was actually a profit of close to INR 30 crores last quarter. There's a INR 25 crores loss this quarter. There's a INR 55 crores swing.

**<Q - Nimish Mehta>**: Okay. Okay. And if you can also throw some light on the ForEx hedging that we are doing? I mean, at what rate have we hedged our U.S. dollar?

**<A - Ramesh Swaminathan>**: So we don't actually disclose that. But as you would know, we don't go the full hog in terms of trying to cover all our exposures. So it ranges between 30% to 50% for the next 18 months to 24 months. In fact, next year is significantly lower. We're really not taking a position at this point because there's too much volatility.

**<Q - Nimish Mehta>**: Sir, what I'm trying to understand is that, have we been able to take the – all the benefit of the U.S. dollar appreciation or because of the hedging it is still not getting...

**<A - Ramesh Swaminathan>**: There has been a hedge loss, in fact every quarter, in the last three quarters you've actually had a hedge loss. So potentially, when the rates are going at around INR 52, INR 53 we did take certain portions of – which are hedged and those are translated into a loss. But a huge chunk were not actually hedged and that actually, so we're able to take advantage of that. So if the rate was INR 61, INR 62, so we're able to take full advantage of, in fact, those invoices, which are not hedged.

**<Q - Nimish Mehta>**: Okay. Okay. Fine. Secondly on, can you throw some light on the possible competition that we might see in Geodon and Trilipix. Geodon has been for there since quite some time without any additional competition. So what do you think and it's also an important product for looking right now?

**<A - Vinita Gupta>**: Yes. One of our important products and we don't see any new imminent competition. I mean, there are some that have gone out, Wockhardt was in it and they went out recently, but that was small. And the other one you spoke about was Trilipix.

So Trilipix, we just launched in the last couple of weeks and so this is a limited competition product. So we have been able to get a decent share as far as – the customers that have awarded us the business we'll still have to sell out the product over the next couple of months to see that actual share show in IMS numbers. Also in Trilipix, we don't see any additional imminent additional competition.

**<Q - Nimish Mehta>**: I see. Okay. Fair enough to say that for the next six months, eight months it will remain with whatever competition it is right now, whatever competition it is right now?

**<A - Vinita Gupta>**: Yeah. Hard to tell, but we don't see any new major competitors coming in.

**<Q - Nimish Mehta>**: Okay. Fine. Thanks very much.

## Operator

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

**<Q - Anubhav Aggarwal>**: Okay. Thank you. Vinita, just one question on the U.S. generic sales. September quarter you did \$150 million, now you've done about \$190 million. Of this delta of about \$40 million, would you say that Cymbalta would have contributed the – or let's say of this \$40 million, Cymbalta would have been given you the largest delta here?

**<A - Vinita Gupta>**: Actually all five products that we launched contributed very nicely to the upside in Q3 versus Q2. And Cymbalta was certainly large, but ZYMAXID was pretty sizable as well. Trizivir was a very decent size. And then we had Fenofibrate, Antara generic, our own generic also did well and Aciphex of course was much smaller. What I say all the three products Duloxetine, Gatifloxacin, as well as Trizivir contributed very nicely to that upside.

**<Q - Anubhav Aggarwal>**: You know why I'm asking this is because TriCor you have lost considerable market share in this quarter, at least the IMS shows your market share is down from 30% to 20%. Just wanted to check that – okay, I'll just ask that question later, but in terms of the \$40 million delta looks even bigger now if I say that TriCor which was such a significant product. That, you're losing market share. Has there been pricing change in the TriCor market?

**<A - Vinita Gupta>**: Actually, we haven't lost any major market share in TriCor.

**<Q - Anubhav Aggarwal>**: Well, probably it's the IMS, which is showing that way.

**<A - Nilesh Deshbandhu Gupta>**: Anubhav, it will also be the base business picking up, which we'd also have between Q2 and Q3.

**<Q - Anubhav Aggarwal>**: This is the antibiotic business, which you referred last quarter was not good?

**<A - Nilesh Deshbandhu Gupta>**: Yeah. **<A - Vinita Gupta>**: Yeah, I mean, Q3 was always going to be better than Q2. Yeah, so in Cefdinir, cephalexin like

products also you see an upside. **<A - Nilesh Deshbandhu Gupta>**: [Inaudible] (21:17) as well. **<A - Vinita Gupta>**: Yeah, so we

see the TriCor base has a solid base as well in our baseline business. **<Q - Anubhav Aggarwal>**: Just to clarify, so TriCor, it stays

where it is roughly about what it was in September

quarter, roughly? **<A - Vinita Gupta>**: So the overall market for TriCor, fenofibrate micro market was declining when we got in. So

the

market has been declining. And from that perspective, you see a lower number of units. But as far as our share goes, that hasn't

changed. **<Q - Anubhav Aggarwal>**: Okay. Got it. Just one clarity, Ramesh, if I adjust for INR 25 crore translation absolute loss that you had in this quarter and compare the gross margin that you reported this quarter, not just September because September quarter you had a very abnormal margin, but with the June quarter, I just see a dip without – despite such good products in the U.S., why would gross margin not benefit here?

**<A - Ramesh Swaminathan>**: So like I said, it's a combination of reasons. So I've picked just one aspect to it. RM, the raw material cost relating to that was higher. Then a host of other reasons also, in terms of – it's all related to, in fact, the mix of products we sold...

**<A - Nilesh Deshbandhu Gupta>**: Utility cost as well. **<A - Ramesh Swaminathan>**: Utility cost as well. **<Q - Anubhav Aggarwal>**:

Sorry, I missed the last word. Which cost? **<A - Ramesh Swaminathan>**: Utility. **<Q - Anubhav Aggarwal>**: But isn't mix much better

versus June quarter in any geography? You see Japan performed

better. U.S. is much better. India, your sales growth was very bad in June quarter, it's much better now. I don't see –

except API growing slightly faster this quarter, I don't see mix being worse than the June quarter. **<A - Ramesh Swaminathan>**:

That's a combination of reasons. So, as I said, we can take this offline, but it's – the principal reasons are as we outlined to you.

**<Q - Anubhav Aggarwal>**: Okay. Just last question, Vinita, on SUPRAX. The off-take on drops have been very weak.

Is that – how is that market doing? And is it drop performing as you expected before your launch, was it not? **<A - Vinita Gupta>**: So we haven't been pushing the drops hard at all. We have got the message out there for the physicians to get to know the product. And since it's a unique dosage form in the antibiotic market, we have spent the first couple of months really trying to introduce the product to the physicians. Our intention is, after the season, we will push a little bit harder. We didn't want to really go through a major shift during the season.

**<Q - Anubhav Aggarwal>**: Okay. That's helpful. Thank you.

## **Operator**

Thank you. The next question is from the line of Girish Bakhru from HSBC. Please go ahead.

**<Q - Girish Bakhru>**: Yeah. Hi. First question was again on the U.S. side in terms of the low dose Antara, has there been any pick up? And if I just look at the branded sales right now, INR 24 million would largely be still SUPRAX, right?

**<A - Vinita Gupta>**: Yeah, majority of it is SUPRAX. Antara, we have started seeing some switch, but not enough as of yet, because people are still on – we had coupons on the older product which last two months. So it takes a little bit of time for patients to switch over to the new dosage form. But apart from SUPRAX in Q3, the other products that have contributed in terms of dosage forms, SUPRAX tabs, has done better than Q2. And then – yeah, Antara low dose also recorded a small revenue. And then Alinia and Locoid also contributed.

**<Q - Girish Bakhru>**: Right. But looking from a numbers perspective, low dose Antara, Alinia, Locoid drops, do you think this branded portion would say increase significantly next year? I don't notice you may need further acquisitions in the branded space right now, like from 11%, can it go to 15% or so?

**<A - Vinita Gupta>**: Well, we would like it to, but it's too early to tell how far we can grow the brand business with Alinia and Locoid. I mean Antara, we believe we should be able to not get back to the same level as Antara was before. But because a good percentage of the market has converted to generic, it will be difficult to get all of it back, but our goal is to try to get as much as possible. So we see the highest potential in Antara followed by Alinia and Locoid. So to get back to the kind of numbers we like to see our brand business at, acquisition is going to be important.

**<Q - Girish Bakhru>**: Right. And on the generic side, any communication from FDA on gas? What has been holding the approval there?

**<A - Nilesh Deshbandhu Gupta>**: Nothing new, no update as of now.

**<Q - Girish Bakhru>**: But as it seems that litigation is over for all the three companies that are waiting for approvals. So would it be a situation where it would again come approval for all, Sun, you and Mylan together or do you think you will get head start there?

**<A - Nilesh Deshbandhu Gupta>**: No. I don't think the FDA is working with a particular date to give the approvals. So I think it will all go independently.

**<Q - Girish Bakhru>**: Okay. Another question related to that, on the OC side, will you have seen Loestrin franchise completely gone generic? I mean, the innovator of course is not promoting that product anymore and Amneal has launched the authorized generic. You have a settlement for a launch in July this year. So does it mean the opportunity there will definitely shrink?

**<A - Nilesh Deshbandhu Gupta>**: Yeah. I think the market itself has switched from the Loestrin to the Lo Loestrin and then the chewable products as well..

**<A - Vinita Gupta>**: To MINASTRIN.

**<Q - Girish Bakhru>**: Right.

**<A - Nilesh Deshbandhu Gupta>**: ...and these are the innovations happening in the OC space. You kind of – you look at the latest product and genericize that.

**<A - Vinita Gupta>**: So we are really watching the Amneal launch very carefully to see what happens, because they're really trying to convert market that has switched to another brand back to generic. And that would really tell the potential of – tell us the potential for our generic form of Loestrin.

**<Q - Girish Bakhru>**: And would you have capability to file MINASTRIN, like chewable product?

**<A - Nilesh Deshbandhu Gupta>**: Yeah. Yeah, absolutely.

<Q - **Girish Bakhru**>: Right. Okay. Just one more before I switch to the queue. Zimax said you don't expect any competition for a significant point of time, right?

<A - **Vinita Gupta**>: Nothing in the near future. [Inaudible] (27:37)

<A - **Nilesh Deshbandhu Gupta**>: So we won the patent litigation, but obviously that goes through the appeals process as well. So I think that would be one barrier which would hold out [indiscernible] (27:45). The other is really nothing and [indiscernible] (27:49). I think there are some filings, but those will come out much later.

<Q - **Girish Bakhru**>: Okay. Thank you. I'll join the queue.

## Operator

Thank you. The next question is from the line of Jagdish Bhanushali from Athena Investments. Please go ahead.

<Q - **Jagdish Bhanushali**>: No. My question has been answered. Thank you.

## Operator

Thank you. The next question is from the line of Bino Pathiparampil from IIFL. Please go ahead.

<Q - **Bino Pathiparampil**>: Hi. Good afternoon, all, and congrats on a good set of numbers. A couple of questions. Vinita, we had a competitor of yours telling about Cymbalta in the U.S. that there was a shortage of product and no player was able to supply enough quantities in the market. Did you have such an experience and – or were you able to supply all your customers?

<A - **Vinita Gupta**>: Actually, Cymbalta was a very pleasant surprise, Bino. I mean, we had expected it to be very competitive over 10 competitors. And when we entered the market, it was only five of us and not all of us had plans for enough quantities to cover the whole market. We did well beyond what we have planned. Our team really worked very hard to do as much as possible to capitalize on the opportunity and that did very well for us in Q3 and continues into Q4.

<Q - **Bino Pathiparampil**>: Good. Is it fair to assume that TriCor and Cymbalta were in the market only for about a month or so or less than that, is it fair to assume that there would have been some channel filling sales or just probably we'll see a better quarter in Q4 because of the full quarter benefit?

<A - **Vinita Gupta**>: No. For sure, when you launch the product, obviously, you have – you are filling the channel and with Cymbalta there was this whole dynamic of let's say a number of competitors coming in, everyone having enough quantities for the market. So there was definitely some channels filling. At the same time, both products will contribute very well into Q4.

<Q - **Bino Pathiparampil**>: Great. Thank you. The domestic market, we have started seeing growth coming back, are all the trade channel issues behind us now?

<A - **Nilesh Deshbandhu Gupta**>: For now, we're okay for now.

<Q - **Bino Pathiparampil**>: Okay. So in Q4 you have a very high base of last year, last year Q4 had a like 50% growth or so. So is that going to impact Q4 growth this year?

<A - **Nilesh Deshbandhu Gupta**>: Too little [indiscernible] (30:21) I think there was a little bit of inventory adjustment that we did in Q4 last year. So we grew at 14% this past quarter. I think, we'll probably grow somewhere between that 14% or 16%.

<A - **Nilesh Deshbandhu Gupta**>: And fact is in Q1 and Q2, the growth rate was pretty [indiscernible] (30:39) pipeline filling of the fourth quarter. And so to an extent I think that's paid off. So you'd expect robust growth to happen

back in the fourth quarter.<A - **Ramesh Swaminathan**>: Robust, meaning 14%, 16%.<A - **Nilesh Deshbandhu Gupta**>: 14%, 16%,

yeah.<A - **Ramesh Swaminathan**>: Very normal standard, that is.<Q - **Bino Pathiparampil**>: Right, right. That's good. And finally,

Ramesh, what explains the sharply lower SG&A

quarter-over-quarter from 2Q to 3Q?<A - **Ramesh Swaminathan**>: It seemed as not particularly low.<Q - **Bino**

**Pathiparampil**>: From INR 580 crores it has come down to INR 480 crores roughly.<A - **Nilesh Deshbandhu Gupta**>: Due to

ForEx impact.<A - **Ramesh Swaminathan**>: ForEx impact in terms of the transaction gains from devaluation is coming in the

overall manufacturing.<A - **Nilesh Deshbandhu Gupta**>: Yeah. We can probably come

back.<A - Ramesh Swaminathan>: Yeah, we could come back on that also.<Q - Bino

Pathiparampil>: Sure. Thank you. I'll join back the queue.

## Operator

Thank you. The next question is from the line of Surajit Pal from Prabhudas Lilladher. Please go ahead.

<Q - Surajit Pal>: Thanks. I just have one question. The thing is that – it's regarding Nanomi. How much time are you planning that conversion from utilizing the technology reach you were acquiring to the level of filing in U.S.?

<A - Vinita Gupta>: So, Surajit, I mean, it's early stage development, early stage at which the company is at currently, but we expect that with the post product we could be filing in the next three years, near three years to three-and-a-half years.

<Q - Surajit Pal>: Thank you.

## Operator

Thank you. And the next question is from line of Anmol Ganjoo from JM Financial. Please go ahead.

<Q - Anmol Ganjoo>: Yeah. Hi. Congratulations on a good set of numbers. Just a couple of questions, one, slightly repetitive. On the Indian domestic formulation, last we heard was that as far as you and stockists were concerned, you had not entered any settlement and stockists continue to – there continue to be product offtake. After that, we have heard noises from some of your competitors that they have entered into some kind of settlements.

So for us, how do the situation remain? In products where we're head to head with some of the others, do we see a market share loss or how is it being resolved or any qualitative color on that?

<A - Nilesh Deshbandhu Gupta>: I think the core of it was that obviously we coexist, the stockists and the companies coexist. And we need them and they need really business to flow through us. I think that's really what's behind the foundation of product flowing through at this point of time. So there is no agreement. There is no settlement at this point of time. But I think there's – I think the strategy of a business, what if that product keeps selling. And I think that's all it is at this point of time.

<Q - Anmol Ganjoo>: Okay. And my second question is on Japan. On Japan, you issued last quarter said that you're not last and last to last but there was some principles where it suffered market share losses in their specific products of whom we were contract manufacturing. And this quarter, we've seen a pretty smart rebound.

I was just wondering how much of the rebound can be attributed to probably our principles gaining back market share and how much of it can be structural, which is a result of some of the changes you've done on the distribution side. And also for the next year, how do you see this business in terms of trend line growth rates?

<A - Nilesh Deshbandhu Gupta>: Yeah. I think we did get back some of the contract manufacturing business, but net-net, there will be a decline. So like I said earlier, we are re-organizing the whole business. And next year, we do expect much better performance.

<A - Ramesh Swaminathan>: I think the growth, at this point, is coming from Kyowa which grew at 17% in yen terms, I'm actually de-grew. In rupee terms, of course, these numbers came out very differently. So I think Kyowa is the one which is having the growth at this point.

<Q - Anmol Ganjoo>: Okay. And my last question before I get into queue. On the branded side, I know a franchise in the U.S. is completely – to a large extent leveraged to SUPRAX. And from a contribution standpoint, 11%,12% is not something we've seen historically. So clearly from an aspiration standpoint, where do we see the U.S. mix pan out? And second is that, you know organically how much effort would go into probably trying to beef up the branded franchise in the U.S.?

<A - Vinita Gupta>: From aspiration standpoint, we'd like to have 15% to 20% of our business on the brand side, but we know that it's a much tougher build than the generic side of the business and then we are working on acquisition opportunities and have been looking hard it's been fairly competitive.

At the same time, we continue to look at acquisition opportunities to grow the brand business in the near term and leverage also the partnerships that we have established like this Alinia, Locoid. I mean, right now, it's very early to say, but we see potential in products like Alinia to be able to grow them to a decent size number into overall brand business.

What we also started to do is develop an internal pipeline for our brand business. What has been missing so far is majority of our internal efforts have been around life cycle managing our SUPRAX and our franchise. But in the last year, we've started working on



developing an internal pipeline as well and have two products, two respiratory products, one dermatology product that we are working on, of course these will not come into market for the next couple of years. The respiratory products will likely come into the market in 2016, 2017.

But nevertheless, if we don't start now, we won't get there. So in the near term, we're going to protect our SUPRAX franchise with the life cycle management strategy, build Antara with a low dose product, try to grow the brand franchise with Alinia and Locoid, continue to look for the acquisition opportunities and build our internal pipeline. The aspiration is 15% to 20% of our revenue.

**<Q - Anmol Ganjoo>**: Okay. Thanks. That's it from my side. Thank you.

## Operator

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

**<Q - Sameer Baisiwala>**: Hi. Thanks. Good afternoon, everyone. Vinita, quickly on Cymbalta, why do you think there were so fewer players on day one to begin with? And how long do you think the prices could potentially hold out?

**<A - Vinita Gupta>**: So the way I think everyone thought that it's going to be a very competitive market. So like most of us thought that this is not a product with high technology barriers. And we're going to see 10-plus competitors in the market and a number of companies that were actually approved did not launch in time. So they were probably not preparing to launch, they thought it's going to – it's not going to be worth it. So it ended up being a very good opportunity because of all of those dynamics. And even now, we have not – all the generic players have not covered the whole market. So there is a shortage in – for the generic. So we expect at least for the next three, four months for the prices to hold up and for the shares to hold up. In fact, there's additional demand and we're trying to do our best to do as much as possible.

**<Q - Sameer Baisiwala>**: Okay. And on SUPRAX drops, Vinita, I remember that you got the approval in the early months of 2013 and you said that you'll be giving a marketing push during the flu season so they can ride through it. And in the flu season, you're saying that now you're waiting for the flu season to get over and after that you're going to give marketing push. Something doesn't add up. So any thoughts on this?

**<A - Vinita Gupta>**: Yeah, so what we realized as we did some market research on our prescribers is that the drops would convert a lot of the 200 milligram but not the 100 milligram. So if we did a very hard push, and did a hard switch, it would have meant that it would have lot of good part of the 100 milligram business, which we did not want to lose during the season. And therefore, the change in strategy to really do a hard push switch after the season, so that we can maximize the season.

**<Q - Sameer Baisiwala>**: Okay. And are you seeing any signs of therapeutic substitution in this?

**<A - Vinita Gupta>**: No, no. It's been fairly stable. I mean, SUPRAX still continues at the same level as far as the share goes. We're not seeing it go anywhere else.

**<A - Nilesh Deshbandhu Gupta>**: No. We're seeing our target customers also existing SUPRAX customers only. We're not trying to switch any other product to the SUPRAX drops.

**<A - Vinita Gupta>**: Yeah, I mean right now our focus has been really to fit the franchise as opposed to try to switch focus on other molecules to SUPRAX.

**<Q - Sameer Baisiwala>**: Okay. And on Nanomi, I know you're not disclosing the devalue, but is it more than/less than the \$100 million, any ballpark number?

**<A - Nilesh Deshbandhu Gupta>**: Ramesh?

**<A - Vinita Gupta>**: We have...

**<A - Ramesh Swaminathan>**: We don't disclose the investment of any of our subsidiary [indiscernible] (40:25).

**<Q - Sameer Baisiwala>**: Okay. That's fine. And just one final question from my side. I think from a balance sheet perspective, I think it was probably a transformational quarter. The company turned net debt zero. So congratulation on that. And how do you see this going forward next couple of years, capital allocation, leverage? How do you want to take the balance sheet forward?

**<A - Ramesh Swaminathan>**: So we kind of calibrate the overall investment we take on the balance sheet itself. So potentially, our philosophy when it comes to, in fact, dividend payout, so it's paying 16% to 20% because we always consider, given the fact that our ROC is the high 30%, 35% to 40% [indiscernible] (41:05) ourselves, we will benefit the shareholders much more.

The second is the working capital expansion is perhaps between 12% to 15% of our total turnover. Capital expenditure generally capped around \$100 million. So you would eventually end up, with, in fact, a surplus every year. But that would generally be used

for, in fact, acquisitions, and we've always spoken about that acquisitions in three buckets: in terms of brand, in terms of geographical spread, and, of course, technology companies. So the technology thing, you have seen some forays into that. So you wait for, in fact, the other things.

**<Q - Sameer Baisiwala>**: And do you think the time has come that you want to think about acquisition as large as \$1 billion and take some leverage on the balance sheet?

**<A - Ramesh Swaminathan>**: If the value proposition is compelling enough, why not?

**<Q - Sameer Baisiwala>**: Okay. Thank you so much.

## Operator

Thank you. The next question is from the line of Mayank Hyanki from Birla Sun Life Asset Management. Please go ahead. Mr. Hyanki, please go ahead. Your line is unmuted.

**<Q - Mayank Hyanki>**: Yeah. Hi. This is Mayank here. Thanks a lot for the opportunity. Vinita, my question is towards you, and this is again is with regards to Cymbalta. Wanted to know that, do you feel that this opportunity could be something, which could turn out to be some Geodon or TriCor and sustain beyond that. And what exactly is the reason behind the supply shortages in the product we call [indiscernible] (42:29) sustained for a longer time?

**<A - Vinita Gupta>**: So the content was certain, Mayank. I mean, we think that additional competition will come in the next couple of months. But we should definitely hold on to a good part of the business, because of a first mover position, the advantages that we have and the fact that we were there for our partners.

And the [indiscernible] (42:56) not everyone planned to be in the market. And the folks that planned to be in the market were not expecting to see the kind of demand that exist for the product. So it's been really – because of the changes in the competitive landscape, that there's been a shortfall.

**<Q - Mayank Hyanki>**: So is it something that do you still feel that which the supply will still remain in shortage or it will be a problem for players even after three months so that new peers will not be able to enter or is that something which will smoothen out with time in the next two months, three months and then you will see more people coming in?

**<A - Vinita Gupta>**: Right now there's a shortage at least as far as we can see for the next couple of months. But I'm certain that like we have been trying to get additional volumes together, our competitors are also working on it.

**<Q - Mayank Hyanki>**: Okay. And what's the pricing right now for generics in Cymbalta right now?

**<A - Vinita Gupta>**: Very decent.

**<Q - Mayank Hyanki>**: And secondly, I will write down short-term and medium – short term to medium term, are you still looking for more acquisitions?

**<A - Vinita Gupta>**: Yes, we are. Yes, we are. Like Ramesh has said, we are looking for acquisitions to build a brand business, as well as for geographical expansion into the countries of our interest, as well as technology platforms to expand our capabilities like this one that we just concluded with Nanomi.

**<Q - Mayank Hyanki>**: So which all geographies are you still looking for to enter?

**<A - Vinita Gupta>**: Latin America, Mexico and Brazil, Eastern Europe, Russia, Poland, Turkey and China.

**<Q - Mayank Hyanki>**: It's not looking at Western Europe the business that Actavis just sold to Aurobindo. So that's something you did not evaluate?

**<A - Vinita Gupta>**: We actually did, and we thought it was a very, very tough business to turn around. Actavis had worked very hard, had very strong team together and has struggled to turn it around. In our European business, we have consciously not taken a huge exposure into Western Europe, because of the pricing concerns. We will participate in Western Europe especially into these complex generics like these injectables, as well as respiratory products that we're developing, as well as dermatology products, but that will be just – it won't be a large scale presence that we would need [indiscernible] (45:26) products.

**<Q - Mayank Hyanki>**: Okay. Great. Thanks a lot. That's all from my side. Thank you.

## Operator

Thank you. The next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

**<Q - Ranjit Kapadia>**: Good evening and hearty congratulations to the whole Lupin team. My question relates to API. We have seen

about 26% growth. Is that all volume growth or it is price growth also?

<A>: It is both.

<Q - Ranjit Kapadia>: Okay. Can you quantify – is it possible?

<A>: Primarily volume growth [indiscernible] (45:57)

<A>: Primarily it is volume growth. I think one of the reasons is that there was an anti-dumping duty on cefadroxil and earlier DSM was dumping the products into the country. So I think that is one reason. And overall, I think the scenario has changed in terms of competition from China. So I think volume growth has been very decent.

<Q - Ranjit Kapadia>: And do you expect this business to grow to 15%, 16% over the next two years overall?

<A - Ramesh Swaminathan>: Actually, it's growing at the same rate as the entire formulation business, so the ratio should more or less remain the same.

<Q - Ranjit Kapadia>: Okay, okay. Thank you very much, and wish you all the very best.

## Operator

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

<Q - Nitin Agarwal>: Thanks for taking my question. Vinita, on the U.S. business, we'll have NIASPAN launch [indiscernible] (46:47) in March. I mean, if you look out the next four-odd quarters, I mean, what kind of opportunities did we see beyond the Loestrin authorized generic launch as well as NIASPAN? Any big launches that we sort of foresee material launches?

<A - Vinita Gupta>: There are many actually. I mean, when we look at the next 12 months, the next fiscal year, there were 20 products that we have planned to launch. But in terms of large scale products, they're not as many as NIASPAN, but a good number of opportunities to help us grow the business.

<Q - Nitin Agarwal>: Are we looking at dates? I mean, are there some date for certain launches there or --?

<A - Vinita Gupta>: Yeah. There's some date for certain launches as well. Yeah.

<Q - Nitin Agarwal>: Okay. Okay. So, Vinita, the thing is we'll be getting into – I mean, we will be probably getting into fairly the base is already high and I guess with NIASPAN launch, you'll probably get another whole bit of growth to our U.S. generic number.

<A - Vinita Gupta>: Yeah, but we have NIASPAN for the full year plus you'll have Trizivir plus Zimax plus duloxetine. Products that we've launched in the last couple of months, that will also contribute into next year.

<Q - Nitin Agarwal>: Right.

<A - Vinita Gupta>: And then the base line business that we're looking at as well is pretty solid with some products showing significant growth. So I mean I don't want to underplay the challenges. I mean there are significant challenges as well with our customers consolidating, with CVS, Cardinal as well as the Walgreens, ABC. There's a lot of pressure on pricing. At the same time, we have a good number of products that we're going to bring to market that gives us the confidence that we'll be able to sustain a good growth.

<Q - Nitin Agarwal>: On the issue about consolidation, I mean, how do you see this whole thing playing out? I mean, what kind of pricing pressure are we talking about here? In a sense, I mean, are there pressures which dramatically alter the profitability profiles of certain products? Because all – I mean, the risk is are we getting into situations where they do talk about volume shifting to a certain generic player consolidating to a certain player, but that in a sense leaves to more supply chain complexity in terms of the trade-off that you get for a lower profitability. I mean, how do you see this thing whole playing out in U.S.?

<A - Vinita Gupta>: So it's a portfolio game of course. So I mean do you see pricing pressure on certain molecules at the same time, because of the challenges that we have seen in certain products with the competition getting out of the market because the manufacturing issue there has been the price increase opportunity or pricing inflation as the customers would like to call it. So it's been a mix of both I would say.

<Q - Nitin Agarwal>: But going forward in the consolidation on the distribution side, what kind of pressure it brings on to the profitability vis-à-vis...

<A - Vinita Gupta>: So that's certainly the – it has put pressure on our margins. But at same time, like I said, we continue to see opportunities to pick up additional business as competitors have a tough time manufacturing for GMP requirements. So we have seen opportunities both ways. I mean the Walgreens consolidation that happened well before the CVS, Cardinal, and so far, we

have survived through it with – we've been able to manage through it pretty well.

**<Q - Nitin Agarwal>**: And lastly, Ramesh, on the SG&A front, if I look at the nine-month SG&A, I mean...

**<A - Ramesh Swaminathan>**: No, SG&A is not the word to describe it. It's actually manufacturing expenses. So it's potentially a host of expenses. I was confused by the fact that you kept saying it was SG&A. We're talking about total manufacturing other expenses has been higher. So we have now disclosed SG&A separately.

**<Q - Nitin Agarwal>**: Sure. Sure. What I meant is that what you classified other expenses, I mean that amount essentially has grown about 16%, 17% CAGR, I mean that's 16%, 17% for the nine months. I mean, there's obviously been variations across quarters, but this is on a trend basis, I think still much, much lower than what you've historically done. This base overall has grown at a much faster pace and which has essentially giving us a lot of operating leverage this whole of this year.

**<A - Ramesh Swaminathan>**: For sure.

**<Q - Nitin Agarwal>**: Has there something changed fundamentally in terms of whether these costs, such costs have been managed or did we hit sort of a tipping point as far as getting some critical mass and as well the operating leverages has begun to play out very materially this year?

**<A - Ramesh Swaminathan>**: I would like to answer this question. It's primarily because of – on account of the translation gain or loss on the – which is coming from the subsidies, which are integral part. In the Q1 and Q2, there was a loss on that account. And that loss was as high as almost about INR 88 crores in Q1 and Q2 together.

Whereas in the Q3, there's a gain of almost INR 20 crores, INR 25 crores, and which is shown in the part of the other income [indiscernible] (51:38) in the press release also. So if you see that Q2 versus Q3, there's a stream of almost INR 70 crores on purely on this account. That's why we can see that this manufacturing other expense is still lower this quarter.

**<Q - Nitin Agarwal>**: Now I understand that. I mean, it's like – I understand there's some sort of inventory or ForEx-related variations, which are there, but I don't think, even if you adjust for that...

**<A - Ramesh Swaminathan>**: It's not inventory related. It's a translation impact on the facilities.

**<Q - Nitin Agarwal>**: But what I meant was little more curious to understand are we getting into a situation where the inflation in this other expenses is sort of tapering down to the 15%, 16% growth number. And you've given the fact that we continue to grow fairly robustly, we probably look into operating leverage incrementally begin to play out in a little more material matter going forward?

**<A - Ramesh Swaminathan>**: Obviously, we are working in fact on operating leverage as well. In fact, you're looking at higher throughput through the same capacities at the factory level and so on. So, any case, Nitin, why don't we take this offline. So...

**<A - Nilesh Deshbandhu Gupta>**: Ramesh, just to take that point, yes, the answer to that is yes, but we're seeing that EBITDA improvement year-on-year as well, right? Obviously, there's lumpiness, there's [indiscernible] (52:49) it won't move sequentially on quarter-on-quarter in a particular direction, but we're seeing that anywhere from 1% to 3% improvement year-on-year. Obviously, as far as costs in India, they do go up at 12% to 15% so there is an operational leverage that is at play here. There are other costs that get added, but certainly we would expect to keep improving on that EBITDA and the 5%.

**<Q - Nitin Agarwal>**: Thanks very much.

## Operator

Thank you. The next question is from the line of Rahul Sharma from Karvy Stock Broking. Please go ahead.

**<Q - Rahul Sharma>**: Ma'am just wanted to know how much of your inventory pipeline would be there for threemajor launches which happened in this quarter, basically your Trilipix, Trizivir and Cymbalta?**<A - Nilesh Deshbandhu Gupta>**: Can you rephrase the question?

**<Q - Rahul Sharma>**: I mean, what sort of channel filling would have been there in this quarter for these three

products which were launched there?**<A - Vinita Gupta>**: So Cymbalta, there was not much of channel filling, because we really didn't have enough to

meet the demand. And Trizivir and ZYMAXID, I'd say two months. Usually, customers would buy two months worth to fill the channel at large. Does that answer your question?**<Q - Rahul Sharma>**: Yeah. Yeah. It should even now going ahead, right?**<A -**

**Nilesh Deshbandhu Gupta>**: Yeah. In fact, we said it at the launch.**<A - Vinita Gupta>**: Yeah. So we have normal level of ordering

for all the three products.<Q - **Rahul Sharma**>: Okay. Okay ma'am. I'll join back the queue.

## Operator

Thank you.<A - **Nilesh Deshbandhu Gupta**>: We'll take last three questions now.

## Operator

Sure. The next question is from the line of Rakesh Jhunjhunwala from Rare Enterprises. Please go ahead.<Q – [00NFRV-M Rakesh

Jhunjhunwala]: Yeah. Hi. Congratulations on a lovely result.<A - **Vinita Gupta**>: Thank you.<Q – [00NFRV-M Rakesh Jhunjhunwala]:

My question, what happened to FIPB? But we are absolutely entitled to have it just because it's some – and sir you will understand the effect of it. [indiscernible] (54:58) because we are part of the index [indiscernible] (55:02) Lupin. But when they buy, they can't buy Lupin, because it's banned on the FII.

<A - **Nilesh Deshbandhu Gupta**>: Yes, Mr. Jhunjhunwala...<Q – [00NFRV-M Rakesh Jhunjhunwala]: [indiscernible] (55:12) where they've clarified the FDA policy everything, still we are not getting the clearance?

<A - **Nilesh Deshbandhu Gupta**>: So what has happened is that we have been following up vigorously with in fact FIPB, but it looks as though were themselves pretty confused because when it was actually placed on the agenda, they kind of said that this is not something that needs to be dealt with at the FIPB level itself. They said FII increases et cetera reached at the RBI level. So they referred it back to the policy-making body, and so in the normal course this would have been placed again in the FIPB meeting, which took place today. But unfortunately because the minutes were not signed, it didn't take place. But I believe it could either take place in the next meeting within, of course, of this month itself, or they would come out with the policy announcements saying that the FII limit need not go through the FIPB thing. So in which case, it would revert back to the RBI.

<Q – [00NFRV-M Rakesh Jhunjhunwala]: Because, Ramesh, don't forget one thing. If they notify the elections, then it will get stuck for another three months.

<A - **Nilesh Deshbandhu Gupta**>: We're pushing, from our perspective, we're certainly pushing.

<Q – [00NFRV-M Rakesh Jhunjhunwala]: Okay. And hello?

<A - **Nilesh Deshbandhu Gupta**>: Yeah?

<Q – [00NFRV-M Rakesh Jhunjhunwala]: As you have announced in your analyst meet that your R&D expenses had peaked at 7% of total, now this 7% becomes 8%, 8% becomes 9%. I mean, is there going to be a limit there or not?

<A - **Nilesh Deshbandhu Gupta**>: Yeah. I think we'll discuss it in the next analyst meet.

<Q – [00NFRV-M Rakesh Jhunjhunwala]: I didn't know you announced it – you had announced it last year it will be not more than 7%.

<A - **Nilesh Deshbandhu Gupta**>: I'll tell you we're going through a transition as far as R&D is concerned with the U.S., with this Nanomi now. We're obviously talking about different risk-reward profile. And we'd be happy to discuss it in more detail at the upcoming analyst meet.

<A - **Ramesh Swaminathan**>: But, Rakesh ji, you should be really happy because the fact we're actually building for the future. The R&D spend is actually the blood line of the company itself.

<Q – [00NFRV-M Rakesh Jhunjhunwala]: No, no, but 9% will become Pfizer then.

<A - **Vinita Gupta**>: So hopefully [indiscernible] (57:07).

<Q – [00NFRV-M Rakesh Jhunjhunwala]: But you don't have Pfizer like margins.

<A - **Vinita Gupta**>: We won't get to that kind of level. But certainly with the areas that we are investing in right now, Rakesh ji, I mean respiratory, dermatology, these complex injectables, it's going to be higher investment.

<Q – [00NFRV-M Rakesh Jhunjhunwala]: No, madam, but we have a limit at some level. I respect that decision that we are an R&D company and are investing in the R&D in the future. But we might not have margins like in every quarter. And once having built those expenses to reduce it will be very difficult. I think our ambition...

**<A - Vinita Gupta>**: We're very conscious of it and are looking at it very carefully to see what the next couple of years look like for us and how do we manage it so that we manage within the percentage that we are comfortable with increasing our EBITDA while making the right investments.

**<Q – [00NFRV-M Rakesh Jhunjunwala]>**: Okay, ma'am. Thank you and congratulations once again.

**<A - Vinita Gupta>**: Thank you.

**<A - Nilesh Deshbandhu Gupta>**: Thank you.

## Operator

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

**<Q - Saion Mukherjee>**: Yeah. Thanks for taking my question. I just wanted to, if you can share your derma...

## Operator

Mr. Mukherjee, I'm sorry to interrupt. We're unable to hear you clearly.

**<Q - Saion Mukherjee>**: Hello?

**<A - Nilesh Deshbandhu Gupta>**: We can hear you.

**<A - Vinita Gupta>**: Saion, we can hear you.

## Operator

Please go ahead.

**<Q - Saion Mukherjee>**: Okay, okay. So on the derma pipeline, can you share how many filings you have done so far and how many projects we're currently running?

**<A - Nilesh Deshbandhu Gupta>**: So we've got only two, three filings done so far. Importantly, one gap that we wanted to plug was bringing in the right clinical capability for these projects. We're very happy that last month we actually brought these gentlemen on board in the U.S. I think that will give a major fillip to the pipeline, but we would expect at least two to three products in clinical trials this coming financial year.

**<Q - Saion Mukherjee>**: So these opportunities that you're trying to address, these are like patented drugs or you're looking at some of the off patented drugs because we have seen significant price increases and those markets have become attractive.

**<A - Nilesh Deshbandhu Gupta>**: Yeah. I think it's both ways. We've been looking at those products very closely, but we want to make sure that we take enough of our long-term lens when we look at those products. But there's obviously a few products which don't require clinical trials which are looking quite interesting also.

**<Q - Saion Mukherjee>**: Okay. And since the R&D spend have been rising, so I mean, I understand this – like derma, for instance, would be taking a lot of spend. What's your progress on the respiratory side? You have put up a team there, the FDA guidelines, draft guidelines have come. So how are you reading the space and at what stage we are and when can you share some more details on that?

**<A - Vinita Gupta>**: So we'll share some details at the annual meet. But we have brought in a lot of capabilities. We have started building the team under the head of – in relation that we brought on board middle of last year. We have started building our facility in the U.S. to do early stage development and we have started working on a handful of products, both in MDI as well as the DPIs. But we'll share more details in our annual meet.

**<Q - Saion Mukherjee>**: Okay. I mean, given that we have guidelines, at least a draft guideline in place, would it be fair to assume that you would look at the U.S. opportunity before you look at Europe?

**<A - Vinita Gupta>**: We're very focused on U.S. and Japan and both are very sizeable markets for the opportunity that we're looking at.

**<Q - Saion Mukherjee>**: Okay. And one last question on the U.S. market. I mean the FDA, you have got some good approvals in the recent past. So how are you seeing the approval rate or the time FDA is taking to approve the products? Is there any change that you're seeing or it's still something which is taking a lot of time?

**<A - Nilesh Deshbandhu Gupta>**: I think we saw that analysis where we had largest number of approvals in the last year amongst most generic companies. But, yeah, I think the time has not changed. I think the FDA is taking the same amount of time. We're not seeing an improvement in the approval rate at this point.

**<A - Vinita Gupta>**: That was expected. We thought that with the [indiscernible] (01:01:14), there's going to be a time lag when the FDA is going to invest into resources, get people up to speed. And then a three-year to four-year timeframe we'll start really seeing significant improvement in approval time.

**<A - Nilesh Deshbandhu Gupta>**: I think next year on, we'll start seeing some improvements.

**<Q - Saion Mukherjee>**: And any comment you would have on FDA inspections like – because of what happened with some of the other companies, this is always a concern area. I mean, can you share what all inspection had happened and any feedback that you can share?

**<A - Nilesh Deshbandhu Gupta>**: So I think most of our sites are – some of our bigger sites like Goa are pretty much getting inspected every year. All the other sites are getting inspected at least every other year. We've been very fortunate in having a very good track record in the last four, five inspections, but the reality is that the FDA could decide on two plants tomorrow and have an inspection. So very hard to comment on this other than to be constantly prepared.

**<Q - Saion Mukherjee>**: Okay. And thanks and all the best.

## Operator

Thank you. Ladies and gentlemen, due to time constraints, we will take the last question from the line of Sonal Gupta from UBS Securities. Please go ahead.

**<Q - Sonal Gupta>**: Yeah. Thanks. Just – it's partly related to what Saion said, but I just wanted to get a sense in terms of how you're looking at the – I mean, are you looking at setting up a plant or facility in the U.S., because you are one of the big players who doesn't have one right now? So any plans on that now that you have – even looking at setting up R&D, et cetera? So – I mean, how do you see that going forward?

**<A - Vinita Gupta>**: So we are right now focused on R&D capabilities, specifically for inhalation, as well as areas like controlled substances. But eventually, we'll definitely need manufacturing capabilities for controlled substances because of the import restrictions.

**<A - Nilesh Deshbandhu Gupta>**: I think that's [indiscernible] (01:03:15) to touch on Saion's point from the compliance perspective, we have to be completely compliant in India. So I think we need to be – we won't look at manufacturing elsewhere on that account.

**<Q - Sonal Gupta>**: So...

**<A - Nilesh Deshbandhu Gupta>**: We've actually done a study whereby there's a – our brand name itself as low cost manufacturer in India. And that brand name, I think remains true for quite some time to come. And that is actually indicated by a report that we have – a study that we undertook very recently with a leading consultant.

**<Q - Sonal Gupta>**: Right. No, but I mean, my question is basically coming from because there are some players who are actually now in private saying that the scrutiny of Indian companies has gone to extremely heightened level, I think the Indian plant facilities versus the U.S. plant facilities. And as a derisking strategy people are looking to acquire or whatever build even greenfield in the U.S., so any plans from that front?

**<A - Nilesh Deshbandhu Gupta>**: No, not from that perspective.

**<Q - Sonal Gupta>**: Okay. Great. Thank you so much.

## Operator

Thank you. Ladies...

**<A - Desh Bandhu Gupta>**: Last questions?

**<A - Nilesh Deshbandhu Gupta>**: We're done with the question, I think.

## Operator

Yes, sir. That was the last three questions. Would you like to make any closing comments?

## **Desh Bandhu Gupta**

Okay. Friends, thank you very much for your coming. I hope you got what you wanted to know about Lupin. We are at a very exciting stage. Our basic research program is getting very strongly moving up. Biosimilars are doing well and there is a overall big growth to come in the near future. Let's be in touch and thank you very much.

## **Ramesh Swaminathan**

Thank you.

## **Operator**

Thank you. 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. Thank you.