“Lupin Limited Q4FY18 Investor Conference Call”

May 15, 2018

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Ramesh Swaminathan: This is one particular event that we look forward to because it's a forum for meeting with people, with all our investors.

During the course of the year, we have several occasions to get together, meet at smaller forums, but this is one big occasion where we meet everybody at the same time. This year, the big story of the day has been the Gavis impairment and I thought I will start off explaining that and talking a little about that.

In terms of the impairment itself, it is about $227 million, but as you would perhaps appreciate, this is because the Gavis assets have been underperforming. When we met with you about 2 ½ years ago, we spoke about this acquisition and that the Gavis assets could potentially garner about $300 million over the next 2-3 years. But as we recognize it has been underperforming, principally because the market in America for opioids, the prescriptions were much lower and there were challenges on the market front itself in terms of price erosion in general sense, more intensifying competition and for those reasons, we did impair. But that said, the intrinsic value of the portfolio is still pretty high. What we have actually impaired is certain molecules which have underperformed and we thought it was appropriate to bring down that value, but there are host of other molecules which we have not launched, which are still captured in the intrinsic value.

Other issues that we thought we would certainly be discussing during the course of the evening are the performance of this quarter and for the full year. This particular quarter, our operational performance was fairly good. We saw growth in all our markets; EMEA was very good, Philippines, Australia, South Africa, all of these markets did very well, LATAM was very good again. India Q4 was a bit off, because it is essentially the way it transforms in the fourth quarter. A lot of green shoots are visible for the next few years and we would be very happy to take you through all of those.

Welcome again!

Dr. Kamal Sharma: Good evening, ladies and gentlemen. It is my pleasure to welcome you to this investors meet. Ramesh has already kicked it off by giving you major

highlights of what the day was like, but here I am going to walk you through a presentation which will build the context for the evening and after the presentation, we will leave the floor open for you to ask questions as you may desire.

The way we have tried to structure our interaction this evening is to share with you the strategic vision of the company, the way we see ourselves going forward from hereon, then quickly dive into the business performance and then share with you the kind of footprint we have already created, the kind of strength that we have which gives us the confidence to go to take on the growth trajectory notwithstanding the current pressures on pharmaceutical industry in general and also share with you the near-term priorities as we see them unfolding and also sharing them with you as we make progress towards them.

So clearly when it comes to strategic focus for the company, we have three strong pillars. Suffice it to say that whatever we plan for the future in our journey is to be pegged at the current foundation that we have created over decade and a half, a very strong company which is amongst the top 10 global generic companies in the world. If you look at the elements of this strong foundation, we all know that our revenues primarily come out of generic and branded generic business which is about $2.4-$2.5 billion. We have a component of branded play which is about 10% of our US revenues.

So far the journey has been promising notwithstanding the macro level pressures which have emerged in the US market particularly and also in Japan. For that matter, I think we are aware that there is not a business or there is not an administration around the globe which is not pushing the prices down. So I think that is the general pressure whether it is the US, Japan. When we started in Japan, you could price a product at 70% discount to the brand, today it is 30%-50% and the incentives which were being given to the trade to push generics has been taken away. So there are pressures all around. But notwithstanding those, I think Lupin has been able to create a very strong foundation in terms of dealing with some of the challenges.

And when it comes to our strategic strong foundation, we need to make sure that the advantage that we have created for ourselves over time, we need to maintain that leadership. Despite the pressures in US, we are the fourth largest generic company by prescriptions. So we need to make sure that we continue to grow on that path. And of course our story in India has been very impressive and so has it been in the emerging market and obviously one part of this foundation would be to continue to grow that market and consolidate further. Using this as our base, this portfolio of strength that we have in geographical footprint, product pipeline, management structure, manufacturing and R&D, we would like to look at the next orbit of our growth which is complex generic focus now and then finally graduate into specialty, but all these three schemes of business generic, complex generic and specialty would virtually run co-current as we would see the future unfolding in front of us.

When you look at complex generics, you would see in the subsequent slide that we have made some good progress in the areas of complex injectables, biosimilars, inhalation. We continue to make differentiated filings and Para IVs and semi-exclusive generics. Our first biosimilar has already been filed in Japan and we are soon going to file it in Europe and we have also made some good inroads into the specialty area.

Lupin has had the distinction of being in the specialty play over the time that we have been in the US. We started our US business with the specialty Suprax and built it up to a strong level of almost like $100 million and then there was generic competition as expected, but we took the life of the brand almost for 10 years. We still have a capsule form of that product with us. Then with the acquisition of Gavis, we had the opportunity to build OB-GYN space with Methergine which also has grown very well. It is almost like $80 million franchise today. But building on that strength, and that is the part of the foundation that we have been laying brick by brick, we are now venturing into real specialty area and build further on that. So that would be something that you would see in the coming years starting with Women's Health and CNS portfolio, Women's Health in US largely and CNS, Neurology in Europe and Japan.

Delineate some of the strong foundation elements for you, some of it I have spoken, what is interesting to note here is that the specialty business in US

is growing at 9%, whereas the generic business is growing only at 2%. So clearly it shows that the next growth trajectory has to come from specialty and that is what we are preparing ourselves for.

In the European market, the five select markets of our interest, the growth is more or less flat. The Japanese market, generic is still showing growth of 9%. What you see here is that overall in the developed markets, the growth is little subdued, but emerging markets have been showing promising growth. In India, we have seen a 4 year CAGR at 11% and LATAM at 10%. By and large, the emerging markets are showing a good prospect for growth in the future.

As a consequence of what we have been able to build over decade - and a half, we are the eighth largest generic company by sales globally. We are the third largest Indian pharma company by global sales, fourth largest company in America by prescriptions, fifth largest India pharma company and sixth largest Japanese generic company. In terms of our revenue portfolio, you see that the US contributes 37%, India contributes 27%. Rest of the developed markets contributes about 18%. What is also interesting to note here is that Lupin's growth has been higher than the CAGR of the market itself. If you see US, the market is growing at 2%, we have grown at 5%. In India, market grew at 11%, we grew at 14% and so forth. Looking at the opportunity of complex generics, we have been speaking about this with you over last couple of years as to how we are building towards it. What is interesting now to share with you is the way we have been getting ready. There have been some very promising developments in this particular area. If you look at the overall market size, you would see that the complex generic market is indeed growing:

Injectables from $47bn in 2013 to $65 bn in 2017; inhalation $19bn to $24bn; ophthalmics and others, I think what we mean to convey to you, when we talk about complex generics, is that we would continue to do more complex oral products along with complex molecules both in the sense of the molecules as well as in delivery systems like inhalation and injectables, etc.

We also have a good portfolio in biosimilars. Biosimilar is an area which is really evolving as you know. There has been good traction in Europe, but

US is yet to see the traction coming forth. It is a very complex area both from technology as well as from commercial point of view. But the way it has morphed in Europe, there are hopes that similar movement will happen in the US and in the other developed countries and therefore in the next 3 to 5 years, one would see a very strong traction on biosimilars.

Lupin has a very strong position in complex generics and biosimilars portfolio. 70% of our portfolio going forward actually is in the space of complex generics and biosimilars and 30% is in the space of orals. So the total market that we are addressing through this portfolio is $104 billion plus. Biosimilars constitute about 32% of that, injectables about 12%, inhalation about 16%, controlled substances about 5% and so forth and very clearly we are graduating from one level of complexity to another.

To share with you some good progress made in our inhalation pipeline: We already shared with you Tobramycin earlier. We have filed Albuterol in FY17 and the most interesting part is that we have also made submission on Tiotropium DPI, our first DPI that is after completion of PD studies. As far as Albuterol is concerned, we have meaningfully replied to most of the queries of FDA and looking forward to the next developments in that product. And I should not miss saying that we have strong pipeline. We are only sharing with you what is meaningfully coming to a stage of completion, but there are other products as many as 6-7 which are in various stages of development. These are too early stage, so we are not sharing the names at the moment, but what is advanced, we are sharing the names.

Vinita Gupta: We are hopeful we have had really good dialogue with FDA on Albuterol and all of the interactions have been very positive so far. So hopefully within the next couple of quarters, we get an approval and launch next year.

Dr. Kamal Sharma: Moving onto biosimilars, again we have the distinction of having our first biosimilar, Etanercept which has already been filed in Japan and is due to be filed in Europe soon and we hope to file in Q4 of FY20 in US. This is product which has completed phase 3 clinical study with about 570 patients and this is one of very strong products in our pipeline and we have the rest of the pipeline graduating into different stages of development.

The next product is Ranibizumab and Pegfilgrastim and thereafter the other three which are in a much early stage of development.

Next is to give you a brief overview of our complex injectable pipeline. We have two sets of injections, we have the Depot injections which are being developed in R&D facility in Netherlands and we also have a pipeline of products which is being developed in our R&D in Pune which is the Lupin Research Park. What you see here is again something which is meaningfully progressing in advanced stages - Risperdal Consta, then we have other products. Likewise, what you see in the lower part, the products being developed in LRP. We again have sizable interesting portfolio products, we are only sharing with you what is advancing rapidly to final stages of approval or submission to begin with rather than approval.

So this is something that we have been also sharing with our analysts and investor community that the ultimate game for any pharma company to be successful and build meaningful growth for the future - it has to have good presence in specialty. One of our largest markets is the US - where the generic segment is growing only at 2%, specialty is growing at a much better rate and therefore it is quite natural that we want to keep our company strong, we need to have a meaningful presence in this area. We have had a good track record of building brands in US. So it is something that we understand the signs and the logic behind it, but this is what we are going to share with you now is our major play where we have decided after due evaluation that we would like to participate in the women's health portfolio as far as the US is concerned and if possible, we would like to leverage it to the other markets also. For Europe and Japan, we are concentrating on Neurology/CNS space.

What you see on your screens is the growth in the Women's Health market in the US, but what is even noteworthy is that this space has progressively been vacated by the big pharma because for them this looks like relatively a smaller size space to participate. So they are concentrating more on oncology and autoimmune illnesses and things like that, whereas I think this provides an ideal opportunity for a company like Lupin.

We having already participated in this area with Methergine as I mentioned to you, therefore we find this as a promising opportunity for us to participate

in. Clearly, the US market estimated at about $12 bn at the moment and global market is about $31-35 bn and, likely to grow to about $40-50 billion by 2025. Likewise, CNS that we have decided to participate in Europe and Japan, you can see that this again provides a sizable opportunity for us to build on.

Our first product, we have acquired a company called Symbiomix in which we have this product Solosec which is recommended for bacterial vaginosis. This is a condition which afflicts almost about 22 million women in US in the age group of 14 to 49. The recurrence is at 43% in 3 months' time and 58% in 12 months' time, and more than 4 million women are treated annually. We have a unique proposition in this product which is one-day-one-dose treatment whereas the current treatment is for 7 days with a lot of restrictions which really impinges on the quality of life. So I think Vinita should share a lot more with you.

The kind of response we have received so far is extremely promising. We have built a good structural organization to support this effort. We have 166 field reps who are going to be promoting this product, of which 41 reps are for the primary care and 125 for the OB-GYN. 70% of the reps have prior women health experience and average experience of 7 years, so that shows the strength of the salesforce that we have. We plan to launch this product in June which is next month. We also have a very strong medical team to support the marketing effort on this particular product. So I think we are going all guns blazing and we believe that this is going to be a very promising opportunity for Lupin, but I must hasten to add that this is the beginning of our specialty foray. We are going to continue to build, create, acquire and really pump in a lot of attention into this particular area of our interest.

Likewise, if you recall, we acquired a business in Germany - Temmler and through that acquisition, we got access to a product called Mexiletine. This is a product that has been granted an orphan drug status. This is positioned for the treatment of myotonia which is a neuromuscular illness, and obviously it has all the advantages which come along with recognition of an orphan drug.

We are planning to launch this in Europe to begin with and thereafter take it to Japan also if it is feasible. In the meantime, you know in Japan we have had a very strong franchise on CNS even with our generic pipeline. Kyowa historically has been known as a CNS company and Kyowa has enjoyed a very strong equity with the CNS physicians and doctors. In order to further strengthen the same portfolio, we have also in-licensed the product from Astellas - Bipresso which is actually doing very well after it has been launched in Japan. So in all the three developed markets, US, Europe and Japan, we are tracking very well as well as building this specialty franchise is concerned. That is about the way we are looking at the future based on our strong foundation created so far, how are we going to be evolving towards the complex generic business and thereafter graduating into specialty and then while consolidating and improving on the generic portfolio, building complex generics and specialty taking it from strength to strength that is the kind of journey that we have planned for ourselves.

Most of you would have seen this, but just to give you a quick snapshot of the financial performance, we've had growing trajectory on the trod since FY13 to FY17 as you see, we have had a CAGR of 16% with EBITDA margin also growing in tandem; averaging around 21% for the first time. Given all the pressures on prices and consolidation of channel partners, intensification of competition, we have seen a decline in our revenues, but we believe that this is temporary. This is something which is affecting industry wide situation. We continue to remain very buoyant about the future of our company and we would see the actions unfold in the future, some of which I have shared with you just now.

Obviously with all these, the US sales witnessed a decline, but what is heartening to share with you that all the rest of the market, which is almost like 60% of the rest of the portfolio, grew very well. So that is the strength of well diversified portfolio. Suffice to say that the US is, of course. a very dominant piece in our overall revenue mix and therefore any decline, even a minor one in US for whatever reasons, does affect the overall health of the company. But the way we have now planned our forays into complex generics and into specialty, we hope to reverse the trend soon.

So as I said North America, when you look at the overall US generic market, you see that where we were experiencing growth, it has actually started shrinking. Between 2016 and 2017, there has been degrowth of almost 9%.

Given that reality of the market plays, Lupin's US business actually saw degrowth of 29% in the year FY18. The corresponding quarter has seen degrowth of 21% and in sequential quarter, there is growth of 5%. But with all this turmoil happening in the market, what is heartening to see is that we have strengthened our position as far as our leadership position is concerned. If you see the trajectory or the graph of our market positioning, you find that of the total ~160 products we have in the market, 51 are market leaders and 109 are in the top 3. Likewise, previous year, we were number one in 45 products, and were in the top three in 83. As a consequence of that from a 6th position by prescription, we moved up to the 4th position by prescription which I think is very commendable for the team in US.

India has been a very strong story for Lupin. We have grown from strength to strength here both on productivity as well as building our rank and we are No. 5 now. We also are very pleased to share with you that another 3 of our therapy areas namely diabetes, respiratory and gynecology constitute sales of more than ₹500 crores each. Another one of the measures is how many brands are in the top 300, I think we have 8 brands now which have entered top 300 brands in the country as against 5 brands last year. We have been ranked as second-best introducer of new products.

Last year, we also took a decision to pursue OTC business and our first product is Rx converted to OTC which is doing very well, growing double digit. We have recently launched another product which is a product for Women's Health based on coral calcium which again, we believe, will do very well in the market.

The APAC region, if you see the Japanese generic market has been growing, but at a slow pace and in the same journey, our participation has been pretty steady. We have grown 14% in FY18, quarter-on-quarter / corresponding quarter 8% growth and on sequential quarter, we have seen

a decline of 2% largely on account of competitive pressures and price cuts, but the market in Japan is going to witness some pressures going forward and I think that is the reason that, as I shared earlier, we are now also building branded presence in Japan, the first of that is being the Bipresso. We also acquired long listed product portfolio from Shionogi. For a long time, the long-listed products were not affected by price cuts but in the recent experience, we have seen that even that is becoming part of the price reforms. Australia business has done very well, growing from strength to strength, grew by 28% Y-o-Y and likewise, I think the other APAC geographies have done well. Those were the three major markets.

I think the other markets of Lupin portfolio in the developed space are the EU 5 countries where Germany at Euro 31 million sales has grown by 18%, the major strength there is ARVs, Women's Health, CNS. These are the key therapeutic areas. We spoke about Mexiletine and the brand name is Namuscla**.**

Canada business at CAD 17 million, grew 57% albeit on a small base, but doing very well. South Africa, we continue to do well. We are the fourth largest generic company and we are leaders in the cardiovascular space there. The two new assets that we have acquired, Mexico was acquired earlier and Brazil was acquired just about 3 years back, have done well. I think Mexico is doing very well and Brazil which is turning the corner. We are also building a cosmeceutical franchise in Brazil based on certain in-licensed products from a Swiss company. Both the assets are going to exhibit very good performance in coming years.

So overall as I mentioned in the beginning that notwithstanding pressures in US, the rest of the markets of Lupin have registered good growth and done very well. API remains our key strength in leveraging our competitive forays into formulations

I think this you have seen, this has been shared with all of you, so I will not dwell much on this. I think what is important here is to note that notwithstanding exceptional items this quarter, I think Q4 performance has been good.

Certainly, I am pleased to share with you that the EBITDA margins have shown an improvement and I hope we are able to maintain this margin despite all the pressures that we see in the coming year.

Ramesh opened the evening by sharing with you the reasons for impairment in Gavis. It is a very prudent and pragmatic way of looking at our business. The future cash flow values of certain assets that we had acquired once we realized that there is general pressure of prices in US generic market and particularly more in the opioid space as you must be reading in the papers, Gavis portfolio does have a sizable number of these products. We realized that some of these IPs are not going to deliver the value that we had assumed in our earlier valuation. Therefore, in a very prudent way we have taken impairment on those. At the same time, there are lots of IPs which are very promising, even better than what they were as per our earlier estimate, but we have left them as it is. So this is as conservative as you can go.

On the tax side, we have created a deferred tax asset in the US created on difference between tax & book value of certain intangible assets of Gavis. Another tax charge was on the winding down of some of the tax that we had provided DTA for the US tax, given the US tax has come down from earlier 34% to 21%. So adjusted for both, net ETR is 26.3%.

We feel proud of sharing with you that we have strong manufacturing discipline. We have 18 sites, out of which 8 are US FDA approved. We operate in almost 100 countries where we sell our products, we have marketing in 25 countries, we have 9 R&D sites in Lupin. 398 ANDAs have been submitted so far, 235 have been approved, 36 pending first-to-files in our US pipeline, 2,800 patents filed globally and 1,700 scientists at global locations.

You all are aware that we received a warning letter for two of our facilities in Goa and Pithampur in November'17. Nilesh would share a lot more because he has been dealing with this. We have all been very concerned about this, but what I am pleased to share with you that we have been at it with the best of advice and best of support from the team.

We have completed the updates that we are supposed to provide to the FDA, the last one will go somewhere end of this month and thereafter we are planning to seek a meeting with the FDA and invite them to tell us the next steps as they would deem fit. We hope that the progress that we have made so far and the commitment with which we have gone after this particular resolution, we should see that the resolution is as early as possible. Just to give you a flavor that while we have these two sites under warning letter, we have had as many as 12 US FDA inspections in the fiscal and most of them, rather all of them have gone reasonably well. So that is the other side of our story of operations.

R&D investments, we have been very calibrated, prudent, clinical about the project that we take, the ones we put on backburner or abandon. We want to take up good quality development and with certain degree of commercial astuteness we have been able to bring down the investment from earlier 13.5% of sales to 11.9% of sales. We have also used some innovative methods of funding so that we do not sacrifice any of our promising projects that we have in our pipeline.

That brings us to the last part of the presentation. Just to share with you as to how we see it evolving looking at our journey into the future:

There is this whole world of continue to reinforce the foundation that we have created where we would bring in more efficiencies, more competencies, more capabilities to make sure that what we have created, we not only sustain it but we further strengthen and grow it.

Clearly using that as our launch pad, we would like to graduate into complex generics, you saw progress that we have made in the last 2 years which in our view is very good. I should not be saying it myself, but the way the teams have worked in a very focused manner, we have been able to get some very good traction on products like Etanercept or Tiotropium or Albuterol and so forth and you will see more of these. So that is something which is the next part of the near-term focus, and yes we are all also looking forward to building the specialty portfolio.

I just shared with you the kind of pieces we have in the portfolio for US and for Japan and for Europe. So all these put together, I believe that Lupin is

reinventing itself in a manner of speaking and notwithstanding the last 2 years and part of the next financial year where the pressures have been there, will be there to some extent because of the market conditions and the complete change in complexion of the business, we believe that Lupin's growth story will reemerge as a very strong story for the future.

Thank you very much.

Nilesh Gupta: We will take questions now.

Moderator: Thank you. Ladies and gentlemen, we will now begin the question and answer session.

Participant: Could you provide an update on the R&D expense, it was down to around 10% in the quarter. So is it the new base that we are seeing, so some outlook and if you are pruning it down, then how are you rationing it whether you are pruning down the generic pipeline or specialty or complex generics. So any color on that would be helpful. Thank you.

Nilesh Gupta: So as you know, we talked about this before. We said we will keep R&D around Rs2,000 crore number that was about 10% of sales as well. So basically the R&D numbers going to remain flat from what it was for the last year and that is the number net of funding that we get as well.

I think the generic world is changing. So we are obviously chasing more meaningful opportunities. We are looking at the portfolio closely, but I feel that we have been able to do all the products that we want out of that. So with this, we are able to maximize on oral solids, we are able to maximize on injectables, we are doing inhalation, we are doing biosimilar, we are doing the depot injectables as well. For the business portfolio that we have right now, I think this is a pretty good number and certainly for the next year at least, we should be able to manage well within this number. The one place which we are probably not investing is much on the organic side on specialty and at some point of time that build will start, but for the next financial year for sure. So R&D spend was at 10% for the quarter and ~ Rs 1,850 crores was what we spent for the year. So we will be able to live within that number comfortably.

Participant: How many products that we dropped from the existing basket right now and how many from the pipeline have we dropped for the whole year, any number you can share with us?

Nilesh Gupta: We have our Head of Portfolio here, so maybe she could answer that question.

Sofia Mumtaz: We have dropped many products which were not meaningful. So we have pruned our portfolio to focus more on complex products, high value products. Opportunities in which we think that there is going to be more than 4-5 generics, given the way US market is functioning right now, we have pruned those products.

Participant: Any number you can share?

Nilesh Gupta: There are a large number of products, adding and deleting here.

Nilesh Gupta: And if I can just add, you have seen we filed typically 35-36 ANDAs per year, we filed 36 ANDAs last year as well. We will remain at a similar kind of run rate as far as number of filings is concerned. It is not that it goes down to at decimally low number of complex products. There still will be fair number of ANDAs that we would do.

Participant: And just another question. Could you highlight your strategy on Solosec launch, Dr. Sharma said that there were some good responses to that pre-launch.

Vinita Gupta: So pre-launch, the response that we have got both from the medical community as well as managed care has been very positive. In the last couple of weeks, we have had the ACOG meeting where the product was exhibited and the attention that Solosec got was more than product that are for fibroids and endometriosis which was really encouraging for us. Likewise, the response from OB/GYNs and nurse practitioners was very strong. On the managed care front which is critical for the adoption of Solosec, we have had conversations with all of the major commercial organizations and have again got very good reception to our pricing strategy. Number of them will not make commitments until the product is launched, but we expect to have good coverage, good access as well at

launch to a certain extent, but through the year. So it is a very promising start. The product launch is in the next couple of weeks, first week of June.

Participant: So in the press, you gave an EBITDA margin guidance of 19% to 21% for FY19. I just wanted to understand the underlying assumptions for the margin guidance. So if you could help me what you are baking in for Ranexa, Levothyroxine, Methergine and your future capital allocation in terms of whatever cash you generate in FY19 inorganic, organic investments what are you planning? What does that 19%-21% build in?

Ramesh Swaminathan: So firstly we do not give product wise details to that extent. I do not think we will be in a position to answer that part of the question. We are undertaking a lot of initiatives to bring down cost and we are actually working with one of the biggest consultancy names in the world to look at host of programs. So we are looking at procurement excellence, we are looking at increasing throughput at the factory level, better productivity of sales force, R&D productivity and the likes. So we do believe that all of this will certainly pay fruits in the quarters to come and that would help us to keep our EBITDA margins at the same level and of course there are a couple of products lined up as you said Levothyroxine, Ranolazine and all of those and of course we build overtime ramp up on Solosec as well.

Participant: So just a follow-up on that for you Ramesh, so at least can you give us some color if you are expecting Methergine generic competition in FY19 and is that baked into that guidance?

Ramesh Swaminathan: Yes, we do believe that there would be generic in the market, Methergine, perhaps in the course of the year itself. We cannot actually time this, but for sure we have baked it into our assumptions.

Participant: And just on a different platform, Dr. Sharma mentioned in this presentation that the big pharma companies defocusing on women health and that is where we see an opportunity. So why is it that those companies are vacating that platform and leaving it for us to grab the market share, what is happening there?

Vinita Gupta: I think it is a small therapeutic area for them overall and if you look at all of the major companies, they are focusing either on oncology, immune-

oncology or neurology/CNS,that is where they find the multibillion dollar drugs. For them, couple of $100 million drugs are not material opportunities. That is where specialty pharma comes in and I think Women's Health is unique in that even the specialty pharma companies that were large like Teva or Allergan. Teva has already gotten out of it, they have sold, divested their business both in the US as well as Europe. Allergan is on the fringe, they would divest if they got the right valuation. We really do not see any material player while you still have unmet market needs. Areas like contraception may be well represented, but endometriosis, fibroids even as we are learning about bacterial vaginosis, there is a lot of unmet market medical needs that one can address. So it is an area that becomes really attractive for a company like ourselves that has a presence already through Methergine and now with Solosec, we have anchor product exclusive for 10 years that we can build and consolidate a portfolio through ideally acquisitions partnership with companies that have near to market, on market access.

Participant: Sure, thanks for that. And just lastly Ramesh, the question on capital allocation. So despite the Rs 2,000 crore R&D spend being flat, we are generating free cash as I understand it. So going forward, what is going to be the capital allocation strategy there. Are we still open to inorganic moves beyond the specialty side or on the generic side or do we see CAPEX organically to utilize that free cash flow. What is the plan there?

Ramesh Swaminathan: Bulk of the capital expenditure is already done. So to that extent, I think going forward you would not be looking at too much of CAPEX, it will be around Rs.1200 crore mark. So far as it is possible to lever the balance sheet to safe limits to my mind it would be about 2-2.5x EBITDA to debt. We can raise about $300 to $400 million on the balance sheet so to speak. But it is something that we would do through calibrated aggression. We would be careful about where we put our money is into. Specialty is of course the way forward and we do get assets that we think are of good proposition to look at that.

Rakesh Jhunjhunwala: I have two questions. What would be the average retail selling price of Solosec? What range, I mean, I do not want the exact price, but what….

Vinita Gupta: So the list price is $270.

Rakesh Jhunjhunwala: And one-time usage?

Vinita Gupta: One dose treatment.

Rakesh Jhunjhunwala: So the generic market has two parts. Every company has some lottery products, I call them where there is no competition, and even if a generic market has not quietened or not corrected price erosion would take place. Other you have a legacy portfolio. So what I think changes in the legacy portfolio is ambiguous. My question is what is the status of the erosion in the US market? Has consolidation taken place, have prices stopped coming down or has the first aspect that consolidation is taking place, people are withdrawing?

Vinita Gupta: No, absolutely, there is definitely signals in the market place that pricing is starting to stabilize and if you look at what some of the generic majors are saying whether it is a CEO of Teva or Mylan or look at the moves from Sandoz, companies are getting out of large portfolios. Teva CEO went public last week saying that he is going to get out of 80% of the portfolio and the balance 20% he is going to do price re-negotiations.

Rakesh Jhunjhunwala: I can see the smile on your face because he is withdrawing.

Vinita Gupta: I think time has come for the industry to take strong action and companies have started getting out of portfolio that do not make sense and having conversations with the customers. What is really encouraging is that the customers are also understanding and appreciating the fact that the manufacturers have gotten to their pain point and for them, really for a healthy environment for generic industry, it is important that the balance shifts a little bit. So that realization has come about. So I think I would not say that price erosion has gone, but I'd say the double digit price erosion days, we are hoping are behind us. More and more companies are going to do what Teva, Mylan, Sandoz are doing and we ourselves are addressing pockets of portfolio where we have pressures and working with our channel partners or customers to see how we can work together to ensure sustainable supplies and the message is seeing well received which is very encouraging.

Rakesh Jhunjhunwala: No raising of your EBITDA guidance because of that?

Vinita Gupta: We will maintain it.

Rakesh Jhunjhunwala: You have not taken any improvement in the US generic market?

Vinita Gupta: If you think about it, when you look at our generic business in the market, in the next year we have a few meaningful products like Ranexa, Levothyroxine and Minocycline, but they have a tail end of the year. In the meantime, we have investments. We have investments on Solosec, plus we have investments also ex-US on the specialty side of the business whether it is Namuscla in Europe or building Derma franchise in Brazil. All of which are very good opportunities for us and in long-term will expand our margins, but in the near term, they require investment. We have the Methergine loss as well that we have built in as we believe that there will be a generic in the market in the next couple of months.

Participant: I have a question on the inhaler portfolio. If you can just disclose whether this will be substitutable products that we are talking about pure ANDAs here?

Vinita Gupta: These will be substitutable products.

Participant: And on the biosimilar portfolio, I guess obviously those will be non-substitutable, so are you looking at creating a salesforce around it and if yes, when do you think you will be able to breakeven after the launch is happening?

Vinita Gupta: The biosimilars as Dr. Sharma said is the market is really evolving in the US. It is very early. There are two products in the market and each has its own scenario, nuances and barriers. As we are looking at Etanercept globally, ex-US in Japan as well as Europe, we are pursuing partnerships with companies that have existing commercial presence in the Rheumatology and psoriasis segment because for one product commercial opportunity, you do not build a large salesforce that would not make sense. From the US standpoint, we still have a little bit of time. We have filed Etanercept in Japan as well as Europe. We will file the product in almost every other market. For the US, we will do interchangeability study which will help and the US is moving towards interchangeable biosimilars. 38 states have already adopted. If a product had

interchangeability studies done, approved by the FDA, then the pharmacy can substitute them. So we will track the market developments very closely over the next months, quarters and like I said we still have to do the interchangeability study for the US. So we have a little bit of time to determine whether we can access the market direct ourselves through a hybrid model or we need a commercial presence and how much of it should we build ourselves, how much we should partner.

Participant: On the inhaler products, are we likely to get over the patent related issues and if yes, are we being litigated?

Sofia Mumtaz: Tiotropium, we have just filed, that is a paragraph IV. We do not know what the brand will do, but I would expect that there will be lawsuit filed on that**.** On Albuterol, we have already settled.

Participant: We have settled already on Albuterol, you said?

Sofia Mumtaz: Yes sir.

Participant: And may we know what is the scheduled launch?

Sofia Mumtaz: That we are not in a position to say.

Rakesh Jhunjhunwala: How many of generics are already approved?

Sofia Mumtaz: Yes, Perrigo was first-to-file. They recently had a CRL. So they have guided that they will not be approved this year.

Rakesh Jhunjhunwala: Is it all settled.

Sofia Mumtaz: We have settled. So there are many patents, we have a settlement date.

Participant: Your emerging markets have shown very good growth this year. So just wanted to understand how has the profitability also grown year-on-year?

Nilesh Gupta: India in particular has achieved great operation leverage. So we had the per capita number in the presentation as well, I am sure you saw that, but obviously the US is the biggest in revenue, India is number two, but in terms of profitability, again US traditionally was obviously the biggest, but I think India is a very solid number two as well. Brazil, we acquired as a

loss making entity while we have built the topline and we still have to breakeven there, we are very close to that number. Mexico, of course again is very profitable. So I think Mexico, India and South Africa would obviously be the high end of the spectrum on the emerging markets and others would be on the lower side.

Participant: And on R&D, so out of the Rs 1850 crores that you spent this year, can you share just a ballpark number, how much is on specialty, how much is on complex and the rest on your Para IVs?

Nilesh Gupta: So about 70% is towards all kinds of generics, about 20% is biosimilars, about 10% is drug discovery. Like I said earlier, we are not spending much internally on specialty at this point and that is something I think will start in the course of this year at some time. We were kind of looking for owning a particular therapy area and I think Women's Health is finally where we have settled. I think now it is really the time to build that portfolio around Women's Health, around Solosec, but around Women's Health in general.

Participant: On Etanercept in particular, what is your expectation from the European market and the other rest of the world market, what kind of revenue prospects you see assuming that these are filed and gets approved by FY20, so the ex-US how big is the potential and the competitive landscape and any advantage that you have and particularly on your capacity etc., will you be able to access the opportunity. So if you can throw some light on this.

Nilesh Gupta: So again, we would not obviously give direct product wise revenue there, but ex-US, Europe will be the biggest market like Vinita said earlier we are going to partner for Europe. We are again going to partner for Japan, I think that will be less than half the size of the European market. So I think these will be the two big markets. We will also do markets like Canada, Australia as well. So some of those will add as well. Altogether, it will be a pretty sizable opportunity. On the capacity front, we are addressing that. Today, we have fairly frugal capacities, but we put a plan together to address capacities in line with approvals. So as more and more of Europe, Japan come on stream, we will be able to address capacities as well. Our capacities are definitely not enough for the US. So we are obviously addressing them from that count as well.

Participant: And in terms of the economics, do you share anything with the JV partner outside of Japan or the partnership is only for the Japan markets?

Nilesh Gupta: You mean with Yoshindo that is only for Japan, YLB is only for Japan and other markets we do ourselves and there again we are looking at partnering.

Participant: And just one final question on the ProAir inhaler given the CRL to Perrigo is there any read across for your product?

Vinita Gupta: We know the challenges. We believe we have got some intelligence of the challenges that Perrigo product had, we do not have that challenge.

Nilesh Gupta: We had a few round of queries on Albuterol as well and right now, we do not have any queries pending on Albuterol.

Participant: Is generic pricing stabilizing Vinita that you eluded during the US market, are you seeing that in the slightly more complex molecules as well or are you seeing this more in the generic plain vanilla basket since those prices seem to have hit a rock bottom and that is where Teva and Sandoz are talking about sort of walking out of the business. So if you could just give us some details on that?

Vinita Gupta: It is around products where companies have significant pressures and when you look at what Mylan has done 60 products that they stopped manufacturing, supplying likewise Sandoz, likewise Teva. Most companies have a good percentage of the portfolio where they have both challenges as well as the opportunity.

Participant: And on the biosimilar front, you said you will look to do an interchangeability study for, let us say, Etanercept or whichever the biosimilar you are developing. My question to you is currently whichever companies are developing biosimilars, are not really looking to do interchangeable or substitutable studies, they are more like doing the equivalent study and trying to get a branded label. So how do you see the market evolving. I am sure just like you are thinking of interchangeable studies, there are other pharma companies also looking to get an interchangeable label. In that event, what happens to the companies that have already launched or will launch earlier the new, the branded

biosimilar because the same could happen to you, let us say in Japan, where you are not doing an interchangeable study, you might get a branded biosimilar and someone else might come and do an interchangeable study and get a substitutable product. So how will this dynamic play out in biosimilars?

Vinita Gupta: So it is hard to predict, but I say that it will be considerable risk for companies that do BLA route and do not have interchangeability. If they have competitors in the market place that have an interchangeable product mean with the fact that 38 states will adopt interchangeable product, they will have pharmacy substitute if the product is available at the pharmacy end means that is going to be disadvantage for companies that do not have interchangeability.

Participant: Is there a big difference in clinical trial spend for interchangeable and non-interchangeable product?

Vinita Gupta: Yes, there is a significant spend and you have to prove that if you are going back and forth with the product with the generic and biosimilar and the brand, there is no change in treatment and results.

Participant: So what would be the magnitude of the difference in cost, as twice as much, thrice as much, I know it will depend on product to product?

Vinita Gupta: It will vary from product to product.

Participant: But on an aggregate basis, just a ballpark number for my understanding.

Vinita Gupta: So it is hard to predict a real number. It will vary from product to product and each company has to sit down with the FDA, go to them with your protocol, get them to buy in your protocol and then pursue it.

Participant: Still confused why many companies are not doing what you are saying?

Nilesh Gupta: So it is a meaningful investment. I think it is still evolving in terms of strategies as well. So I think companies are still deciding. For example, in Japan, you still have to go, promote the product in the like side**.** So interchangeability does not give you an automatic advantage. I think interchangeability in particular is very important in the US. That is a switch

study that of course you need to do when interchangeable obviously is significantly more investment than a switch study.

Vinita Gupta: I think at least for now it looks like European, Japanese markets are still going to be abandoned market in the foreseeable future, but the US is likely going to evolve sooner and that would be a tremendous opportunity for us because at that point in time, then you can ramp up your investments in biosimilars and have a hybrid or low investment commercial model into the market place.

Participant: What percentage of the US portfolio would comprise specialty product today and second question pertains to are you planning any further rationalization in the product portfolio?

Vinita Gupta: 10% of our US business is specialty today. I did not catch the second question.

Participant: In view of the current market situations, do you think there will be any further rationalization of the US portfolio?

Vinita Gupta: We will constantly look at the portfolio as Head of Pipeline, Sofia was mentioning that we on a consistent basis are looking at our pipeline and portfolio to determine does it make sense to put good money behind a particular program or not, is it better to divert our investment to another program depending on the market conditions, depending on the competition. If we are not in the first three to launch a product, if we are going to be 4th, 5th and 6th, we have to have a very strong rationale, very strong conviction that we have some differentiation or some reason why we think we are going to get return on our investment. So it is a very disciplined process of questioning our pipeline over and over again to determine if it continues to make sense to invest, in particular, for large investments.

Participant: So all the current pipeline is aimed at the top first three positions.

Nilesh Gupta: The majority of the pipeline would be where we would either be in the first wave or we would see it as relatively complex product where there would be limited competition.

Participant: Are we also planning to rationalize our products in US just the way Teva and Mylan are pulling out. Would we also be looking at pulling out certain products?

Vinita Gupta: Well, we have had similar conversations I would say. Our approach for the last many years has been that we do not sell products that do not make money. So if a product is not going to make margin, we are not going to launch it and number of companies in the past have had loss leaders as they call it. But we have a few up products where which are below the level of margin that make sense to be able to manufacture product long term. So we are having similar conversations.

Participant: Okay and my second question would be between biosimilars and specialty pharma, which line would we be pursuing because I believe investment in both the lines are significant and trying to be there in both the places may not give us a clear indication of where we want to be.

Vinita Gupta: Actually the way we look at it and the development risk, the risk overall in the two areas is calibrated the way we are investing into the two areas, 20% of our whole R&D spend is biosimilars while we do not have any R&D spend that goes into specialty. On the biosimilar front again, where we see good opportunity long-term mean we believe that at the 5 years, 10 years from now, the generic market could be a good percentage of the big opportunity of the future will be biosimilars, will be biologics. If you look at the market today, a good percent of the market is biologics. So for us to continue to draw the generic business, we are going to have a presence on the biosimilars front. We think it is essential investment for long-term growth on the generic side of the business. At the same time, it is going to evolve in the next 5 years. So we are calibrating our investments in terms of the number of products that we invest into at any particular time and we are mitigating our risk also by partnering some of the investment whether it is with commercial partners or financial partners. Specialty on the other hand, the way we look at it ultimately whether it is inhalation, whether it is biosimilars, all of them are still going to me-too and you are going to have competition in each of these areas at the end of the day. Even where we look at Etanercept, we likely will be one of four**,** we still think that it is a very strong position in an $8 billion product, but we will be one of four. On the specialty front, we have the opportunity if we pick and choose the right

product, we have the opportunity to be long-term exclusive. We do build the proprietary position and to build the sustainable long-term position for the company. So it is a different opportunity with the specialty on the specialty side of the business and at the end of the day, we want to have a well-diversified portfolio between complex generics, inhalation products, biosimilars and specialty.

Participant: As we discussed earlier in the presentation on the pipeline on the inhalation side of biosimilars and the complex injectable side, how should we look at the US side of the business for the next 2 years given high single digit price erosion, the FDA trying to give faster approvals in order to lower the pricing overall. So what is your view on the US side of the business for the next 2 years since most of our opportunity will start to unfold post FY20 onwards?

Vinita Gupta: As we mentioned, the next year we have pressures. We have pressures on the base business, the pricing pressures which hopefully should be lesser than what we have seen in the past. We have new product launches like Ranexa will be a big one for us in the year FY19. So we expect to launch Ranexa, Levothyroxine like product that should offset and help us grow the generic business. Then on the brand side, we have the Solosec launch which is going to be critical and the first year, we are still going to work on managed care, adoption and then the prescription bill. So it is going to be a build year for us. Simultaneously, Methergine is likely going to go generics. So next year, fiscal year 19 we still see as a year where we have challenges, hopefully we should be able to grow our business based on the products that we intend to launch but we have challenges. Fiscal year 20, we hope to be able to launch Albuterol. If we get the approval for the product, we hope to be in the market with Albuterol. And other products in our portfolio should have Solosec ramped up to a nice level. We believe in year 3 to 4 we will be at peak share. So we will be well on our way. We see fiscal year 20 as real critical year to start growing the business in a meaningful manner.

Participant: Ma'am the next year if you go and see as you rightly suggested there are many pressures that are coming in, whole Glumetza and Fortamet is under pressure. On top of it, Methergine is also going generic plus high single

digit. Will we be able to grow in double digit on the US side or it would be mid-single digit kind of a growth?

Vinita Gupta: I am not going to give guidance on the percentage growth. I will be happy with growth. Our effort is going to be to try to grow the business for the fiscal year 19.

Participant: And on the Gavis side of the business, do we see any more kind of an impairment that will be coming through on the portfolio side?

Vinita Gupta: No, we do not believe so. We have taken all of the hit in one go and like Dr. Sharma said, we just took a very conservative prudent approach that not take the upside on the product that we had filed that have added value to the Gavis portfolio, we just took all of the down side.

Participant: Just wanted to check on ex of US specific for FY19, what is the kind of growth rate that we should be looking at?

Ramesh Swaminathan: Overall, I think the company is slated for perhaps single digit growth rate for the next year. If you look at the various regions, there is going to be good growth in most emerging markets. Latin America would grow at perhaps 20%. We could expect South Africa to go at 20%. India could be 15% to 17%, but of course the more is indeed going to be in the US, but that is going to be sluggish.

Nilesh Gupta: I do believe that we will grow in the US, there will be lumpiness and especially when Methergine goes generic for example, Solosec ramps up, and obviously you are going to have those kind of pressures. You will see in India also things go up and down, but we still end up growing at a respectable number. So I think single digit growth is what we are looking at this point of time and with some growth in the US.

Participant: My question is on the warning letter. In context of the current ongoing remedial measures, if there is some delay than what we currently expect, how our growth assumption changes or margin assumptions if we have built in something?

Nilesh Gupta: First of all, I am glad you asked the question of warning letter because nobody asked it, but obviously it would hurt the business. We said this very

clearly before the warning letter first of all we are deeply disappointed that it happened, but it happened at a time when there were no very big meaningful launches that I expected. Certainly, we have lost out on several products which have gotten delayed because of that. If it overflows into CY19 especially after the first quarter, I think it will start hurting. So I think obviously it is the most immediate priority to resolve that. I feel really good about where we have reached so far.

Participant: Just one question. You were saying that Allergan is also looking to divest their Women's Health business portfolio and they are looking for a right valuation. Would you also be interested in looking at that?

Vinita Gupta: It is a billion dollar business. Well, it is way too sizable for us, way too large for us.

Nilesh Gupta: Thank you everybody, please join us for dinner.