



“Lupin Limited Annual Investor Conference Call”

May 24, 2017

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Moderator: Ladies and gentlemen, good day and welcome to the Lupin Limited Annual Investor Conference Call. All participant lines will be in the listen-only mode. Please note that this conference is being recorded. I now hand the conference over to Lupin management. Thank you and over to you.

Ramesh Swaminathan: It is a great pleasure to welcome you all to our annual investor meet. It is one event that we really look forward to because it gives us a great opportunity to interact with you. We use this forum to discuss where we are and what are the intents going in the future. So, we find it extremely useful from the management's perspective. I have been speaking about this to a lot of investors. They also look forward to that and I hope there is consensus there.

The year that went past us was a great year for us. How else would you describe the year that we grew 24%, we clocked more than a billion dollars of revenue in America and the highest ever profits. But the sheen was taken away a bit in Q4 because of higher R&D spend, because of Forex volatility and the provision that we made for generic launch of Isabelle that we had in Australia some time ago.

This has been a very eventful year. There have been lot of challenges and there have been lot of interesting moments as well, but let me not take away thunder and speak about it. We have got Dr. Sharma who will take us through the presentation and take us through the challenges and the prospects for the future.

Dr. Kamal K. Sharma: Thank you. Good evening, ladies and gentlemen. It is indeed my pleasure to welcome you to this interactive between management and yourself. We all look forward to this once in a year because aside from interacting with you on the earnings call every quarter, I think this is one opportunity that we get to present to you the direction, the strategy of the company and also which is equally important, rather more important, to learn your perspective, the way you perceive it in terms of the business and the industry.

To begin with, I think we have a small presentation like every year and thereafter we would open the floor for questions and answers. The presentation we have divided into four parts. First, to share with you, the way we have performed over last decade or so, thereafter look at the market dynamics as they are emerging, then straight dive into the performance of the company and finally to share with you the road map going forward.

I think Lupin's team has done an excellent job in terms of carrying out some very strong process innovations and extremely good execution work, which has led to some of the milestones that you see on your screen. Today, we are very proud to say, that we are the fourth largest generic company globally in terms of market cap, 6th largest by revenue. We are the second largest pharmaceutical company out of India. We remain, of course, that is our legacy business, tuberculosis, where we remain number one worldwide. We are the 6th largest Japanese company



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in generics. We are 5th largest in US by prescriptions, 6th in India Pharma Market. We have made lot of strides in India in the past year and we the fourth largest South African generic company.

In terms of certain financial milestones, it is very heartening to see, that over the last 10 years, between 2007 and 2017, our revenues have grown 8.5 times, the EBITDA has grown 9.6 times, the R&D spend, of course, has gone up 16.3 times which just shows that we have been investing ahead of the curve in preparation for the future and we look forward to harvesting some of the benefits of this investment that we are making.

These are some of the awards which come by way of how we perform and how we dispose ourselves as a corporate citizen. I am not going to go through each one of them, but I think there are some very noteworthy recognitions from the industry and from the media and some of the outstanding things here that I see is about Vinita Gupta getting Outstanding Woman Business Leader of the Award from CNBC and Forbes India Business Leadership Award for Vinita and Nilesh. Also, our CFO has been recognized by industry and the media. So all in all, it is very heartening to see recognition coming our way for the good job being done by the team.

Having spoken about the way our journey has been so far, it is time to look at the market dynamics as it is emerging. Most of you know and I think it is worth emphasizing here that the market all around is undergoing tremendous structural change. If we look in the US, which is one of our dominant markets, there is consolidation going on for the last 2 years now amongst the channel partners and there is no stopping the momentum. There was also consolidation happening amongst the payers. The regulatory rigor from the regulator continues to be severe on compliance. I think the good thing, of course, has been that the approvals are in abundance, but that as we often speak is a double-edged sword. On one hand, it gives us a handle to neutralize some of the loss that we get in the revenue and profit lines. On the other, it produces lot more competition in the marketplace.

So, if you look at these four dimensions of the market dynamic, you would see that there is a tremendous pressure on the prices and therefore the growth of the generic business in United States. Likewise, if you see India, I think since 2012 or 2013, NLEM (the National List of Essential Medicine) is ever expanding and it was quite a surprise when it came in 2013, but, thereafter, it has become a way of life and then a ban on fixed dose combinations. Now, the latest dynamic is about the Jan Aushadhi and you know, promoting generics and doctors have been asked to prescribe in form of generic names. And pressure on the prices again.

Likewise, in Japan, where the Japanese government remains committed to expand of generics, they keep on putting hooks on the pricing. We now hear that they are threatening to reduce prices every year. I think while they would like to promote the generic consumption, they are keeping kind of a cap on the overall bill for healthcare because the entire bill is picked up by the government. This structural change all around that, I just spoke about, obviously results at the market level in terms of certain challenges which are in terms of growth perspectives that in



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developing markets, growth is only happening through innovative strokes whereas in emerging markets, it is a volume driven growth.

We have spoken about the pricing pressure on generics and I think the way forward is of course to shift to complex generics and we know that complex generics are very technology intensive, with clinical work involved in many of them. They are not as simple and straight, inexpensive as the small generics. So it takes a lot of doing, both in terms of building a platform as well as in terms of getting a clinical approval of the product.

Also, I think most of the key generic companies are now pushing their first towards creating a specialty portfolio and I think there are certain niche areas that most of the companies are pursuing. Again, this is something that Lupin also is pursuing and we had been in fact, in some way, the first one to be present in this area, we have been there since 2003. To catch on the momentum in this area is the tough call. We have been doing our bit, last year we launched a product in the Women's Health Area and we have a set of opportunities in our pipeline plus we are also looking at certain inorganic opportunities to build that portfolio.

We have been working on biosimilars for the last 9 years or so and as we go along, you would see that we have some substantial progress to report on our biosimilar portfolio. I think one thing that Lupin can be truly glad about and happy that we have been able to deal with compliance issues very smartly and I think the entire team has stood by the "quality oath" as we call it. We lay a lot of emphasis on compliance, on quality assurance, on our regulatory discipline.

As a consequence of all this, I think the generic growth has been kind of slowing down. 2016 was the first year that we saw de-growth in generic business in the United States, it degrew by 2%. We have also been seeing that in India also, the growth has been muted. Likewise in Japan, I think where we were experiencing the growth of about 12%-14%, it is expected to be around 7% and I think the way it appears, this kind of slowdown in the growth of generics has come to stay. And as I said earlier, I think the way forward is really to go on the value curve and deal with by introducing more complex generics in each of these markets and more importantly build a strong portfolio in specialties.

This is our broad strategic direction that we have been following. I think very clearly so far till 2016, the team has worked hard to create a position in the global arena in terms of our leadership in generics. We have presence in three very strong geographies that is US, India and Japan and between the three geographies, I think our revenue accounts almost 80%. We are working for the last couple of years developing complex generics as you are all aware, we have an R&D center in Florida in Coral Springs which caters to inhalation technology and the products thereof. We have a company in Netherlands, Nanomi, which has a nanotechnology platform and we are working on complex injectables.



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We also have backup for all these in India in our Lupin Research Park in Pune aside from the fact that we have ventures in Japan and in Mexico which caters to the local needs. And our endeavor is that while we go through this pressure journey from now till about 2019, we build a very strong portfolio of specialty products and of complex generics to go forward from 2019 onwards and pick up our growth trajectory once again.

From here, we move into the financial performance. There are some major milestones in the financial year that just gone by. As I mentioned in the early part of my talk, I think we launched Methergine in women's healthcare in specialty area in US in April 16. I think we are doing well there. We seem to be picking up momentum and we certainly see a lot of growth coming during this year from the product.

We added another very large state-of-the-art facility in our Research Park in Pune. US FDA cleared our Goa site and a new unit was commissioned in Somerset in Lupin. We made our first MDI ANDA of Albuterol ProAir. So that is one of the achievements of our R&D center which is in Coral Springs. We have also commissioned a plant in Sikkim which as you know is a tax-efficient area. Our Japan business has been growing, so it requires commissioning a new plant. So we have a new plant now in Tottori and we recently launched a generic Minastrin which is about \$360 million in brand value and we have 180 days exclusivity there.

In India, I think there are some major developments that we have been able to have in our business. I think I can say very safely, Rajiv is here, that I think today Lupin probably has one of the richest anti-diabetes portfolio in the country with DPP4 and SGLT2 receptor molecules from Boehringer Ingelheim. We have as you know human insulin from Eli Lilly. We have also in-licensed their short acting analog. We also have a long acting analog which have been licensed from a South Korean Company. So if you look at the portfolio of India in diabetes, I think the strongest and we obviously expect very strong growth in that particular lifestyle segment.

In Japan to fuel our growth, we acquired 21 brands from Shionogi; half of them, am I right Fabrice, are in the CNS area. That strengthens our CNS portfolio. We are a CNS company in Japan where Kyowa is known for its strengthened CNS area. We have also in-licensed from Astellas: Quetiapine which is extended release product for marketing in Japan. When we benchmark ourselves with peer group, Lupin had a sales growth of 24% plus during the year and our EBITDA grew by 19%. As against that, when we look at Indian peers, their expected sales growth is 8.7% and the expected profit growth is 6.7%. Among global peers, I think the sales growth was 8.1% and the profit was 10%. So, I think as Ramesh said in his opening remarks, this has been indeed stellar year despite lots and lots of challenges and many more to come.

Looking at the yearly performance – clearly, we have done very well. This year, we grew 24.4% topline and our net profit has grown by 13%. On the quarterly side, I think if you see our quarter-on-quarter, the sales have shown a very marginal growth of 1.3% whereas on sequential basis, we have de-grown by 5.5%. The major change that you see here is in our EBITDA margins



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between 32.8% to 19.9% on quarter-on-quarter basis and 13% to 19.9% on sequential quarter basis. I think there are reasons as Ramesh has already mentioned, we have had three major reasons and we have a bridge here to explain to you.

The first and foremost of them is that we were in litigation with one of the companies and we lost litigation in one of our geographies while we won that in other geographies and we have to pay a compensation which we have paid in this quarter. There has been Forex, rupee has depreciated almost by 5% in the last 4-5 months, that impact has come there. Also, our R&D expense has gone up substantially in pursuit of what I just spoke about the new line of business and therefore this has led to this particular drop in EBITDA margins and profit.

As you can see here in between the year 16 and 17, Isabelle is a product that I spoke about where we were litigating, the impact was 0.9%. The Forex impact is 1.3%, R&D is 1.8% and likewise you see the effect obviously is much more pronounced when you look at the sequential quarter and the last year corresponding quarter, where the Isabelle effect is 3.7%, R&D is 2.5% and 2.6% and the Forex is 5.7 and 4.7%, respectively.

Now diving into individual major markets for Lupin, as you all know North America is one of our major markets with almost 43% of our revenue coming from United States of America or rather North America. What is most heartening to share with you that we crossed the \$1 billion mark for the first time in US business. Turnover was \$1.2 billion for the year. On the back of Methergine launch, brands grew by 90% to 78 million. We have been receiving good number of approvals, 18 products were launched during FY17 with 11 in the last quarter. We continue to maintain handsome market shares in most of our products as you can see on your screens. We are number one in 45 products and 83 products are in the top three. And 154 ANDAs are pending for approval which corresponds to almost \$76 billion of business in brand size.

Likewise, in India too, we have grown well. Our year-on-year growth was 11%. As I mentioned, we have been able to strengthen lot of our chronic area therapies. What is also interesting which I have been sharing with you every year that our chronic portfolio has been progressively increasing. Today between chronic and kind of semi-chronic portfolio, we almost have 80% of our products and the balance are in the anti-infective and acute area. We have second rank in cardiac therapy and fourth rank in diabetes and we continue to remain second in respiratory.

APAC area, Japan again saw a very good growth of 15%. Overall, the APAC area grew by 28%. We have been strengthening our CNS portfolio in Japan as I mentioned earlier. We acquired the Shionogi brands. We have also in-licensed the product Seroquel, I think this is from Astellas. We are the 6th largest generic company in Japan. We spoke about the new facility that we have commissioned. Philippines is another geography that has been doing very well. I think we grew 23% in that market whereas I think the market growth has been substantially lower at about 6.7% and we are ranked fourth in the branded generic play in Philippines.



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EMEA, again I am pleased to report good progress in Europe. As you know, Europe is a very fragmented market, different regulations, different pricing standards, and different customer preferences. Despite that, I think we have done well in Germany where our business grew 24%. We continue to focus in top EU 5 markets. We acquired a company called Temmler year before last, that has added to our strength in CNS. More importantly, it has given us access to a molecule which we are trying to develop into a specialty area and I think Vinita will speak about that in her commentary.

South Africa has been historically doing extremely well for Lupin and it continues to do well even now. Last year, we grew 21% in South Africa. Latin America, the two markets that we are operating Mexico and Brazil, is really a new baby on the block. We acquired Lab Grin about 3 years ago and Medquímica about year and a half ago. Lab Grin has been doing well, we have had some challenges in the distribution area, but they have all been overcome and we have seen good growth whereas because of the distribution issues, our internal growth that we reported 5% but if you look at the reported growth, IMS is about 12.8%. So that is good going for the company. Even in Brazil, our sales have shown tremendous growth, 53%. However, we still have to build on the profitability side and hopefully with some good and hard work over the next 2 years, we should be doing very well in Brazil too besides from the topline growth.

API is our heritage business as you know that a lot of APIs required in the company. What you see here is only that part that we sell to the outside, but we do manufacture huge quantities which are consumed in-house, almost 75% of what we manufacture, we consume to make our own formulations. But I must say that the API group has been doing a lot of work in expanding itself in global international tender business and aside from leadership in TB, we are also working in the area of HIV and inhalation products. That brings us to the discussion of what lies ahead.

As I said, we all understand that this business is getting into a new dynamic. The structural changes that I spoke about and I think the whole idea as to how you create value, deliver value and capture value as what we define as the business model is going to undergo change. In lots of our geographies, we will have to deploy salesforces to go to the doctors and promote our products which today we do lot less, in fact certainly we have a small salesforce in America, but our large business happens through the channel partners but I think the whole business model is going to undergo a change and we are preparing for all that, as you would see how our preparation has been. I think very clearly the first lever that you press when you want to change the business model is the R&D and I know that this is something which every time Nilesh brings up or Vinita talks about expanding expenditure, we have feverish debate within ourselves and but at the same time, we also know that lot of this expenditure is required to really create new business and grow our existing business.

What I am really happy to tell you is that today we have solid infrastructure available in the company to deal with whatever challenges we are going to face in the coming few years. We have 18 manufacturing plants, 12 of them in India, 3 of them in Japan, one each in America and



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Mexico and in Brazil. We have, I think, a stellar record, I always keep my fingers crossed when I make this statement, but I am very proud to say that Lupin has an excellent record on compliance. I think we worked very hard right from the top to across the organization to make sure that quality is the byword across the ranks and files of the company.

We made 9 acquisitions in the last 10 years, some of them to expand into geographies and now largely in the area of building our specialty portfolio. We are three areas that we have been looking at is the Women's Health, CNS and the Pediatrics which is something that we started off way back in 2004. This is just global positioning of our manufacturing and R&D centers across various geographies and I think what worth noting down here is that we have 368 US ANDA filings, out of which 154 are awaiting approvals. Rest, I think about 139 are in the market. We have 45 US first-to-files and out of those, I think 11 are exclusive and we have about 1,700 scientists in all our research. So, it just shows a strength of our R&D activity.

R&D spend as I said a while ago has been certainly going up and for going forward, of course we think that we are going to keep it at an absolute number that is at the moment about 13.5% of the sales. We obviously are going to spend more money in conducting clinical trials for our complex products as well as for our specialties and for biosimilars. This is just a benchmark of our pending ANDA pipeline versus our peer group for the competition. We are actually fourth in terms of pending and this 154, they correspond about \$76 billion in brand value.

That gives you a pen picture of how we divide our investment into different areas of our research activity. Obviously, at this moment oral solids and liquids take the larger cake, but going forward you would see biosimilars is almost 15% by value and likewise in the area of respiratory and complex injectables.

So this is what we envisage going forward for our company. We started our business getting first international foothold way back in 2004 with Vinita taking lead in America, thereafter we acquired our business in Japan and as I said in the beginning of this presentation that as of 2016, I think we have been able to acquire leadership position in generic business; however, going forward, we are going to press gas on building a very strong portfolio of complex generics followed by biosimilars and thereafter moving into specialty area and this exactly the way what we depicted earlier that 2017-2020 would be the building up area and beyond 2020 is the area of building and harvesting.

Success obviously hinges on innovation and execution. Both process and product innovation as well as execution, execution has been a strong hallmark of Lupin and I have reasons to believe that with the kind of infrastructure that we have on hand and the kind of training and the culture that we have built in our organization, there is no doubt in my mind that despite many challenges enroute to our next business model, we would be able to sustain and create a growing organization for time to come.



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Thank you very much. I really appreciate your attention and we now open the floor for questions and answers. Thank you.

Prakash Agarwal:

This is Prakash from Axis. My question is on the US business. We have seen strong performance for the year, but when we see the exit rate for 4Q, we have seen some softness coming along and we also noticed that couple of your large products have seen more competition. So a) what is the kind of pricing pressure you have seen in the overall portfolio and b) how do you see this US business specifically for fiscal 18?

Vinita Gupta:

First pricing pressure on our base business as we have said in the last couple of quarters, it really leveled-off at single digit and if you put Glumetza and Fortamet aside because the exclusive are that is where you see the biggest erosion when you have additional competition. On the rest of our portfolio, we saw a single digit price erosion. On Glumetza, Fortamet, we saw additional competition with the AG on Glumetza in February. The pricing as well as market share assumptions that we have made, the pricing pressure was more than what we had anticipated. So as a result, you saw the erosion in Q4. Likewise, with Mylan coming in late last year in Fortamet, we saw some erosion in Fortamet as well. If you again put aside the exclusive on the rest of portfolio, we saw single digit price erosion and certainly until last week, we are part and majority of our peers, global peers as well as Indian peers were really looking at a single digit price erosion, but with the new development in the US with WBAD and EconDisc coming together creating 40% market share customer, certainly will put more pressure on pricing in the near term. We do not know when they are going to implement their joint procurement, but whenever they do, we would expect some additional price erosion. So I would like to be able to say that we are not going to see pricing challenge, but that is the way of life for us going forward and we are going to see challenging 2018 as far as price erosion goes, 1) because of the high base of business that we had in fiscal year 17 especially with Glumetza, we had a fantastic run, we never expected for it to be exclusive for 11 months and we were very pleased that we were able to leverage the opportunity but now we have the offset, we are going against it in fiscal year 18. We have a number of product launches that we have planned in fiscal year 18 both out of India as well as Somerset. We have over 30 products that we have planned to launch in the US market, some are larger than others, but all said and done, not major exclusives, but we have products like Minastrin that we have just launched, Epzicom that we have just launched, Bupropion XL that we received approval for not too long ago, Quetiapine XR that again got recently approved that we can try to launch earlier than we had anticipated. Likewise, out of Somerset, while the last year has been challenging acquiring the business, we learned a lot as we acquired the business and brought it under the Lupin umbrella, but it has been a very strong operational year for us in Somerset. We have expanded capacity at the site 10-fold to be able to deliver the plan that we had for the products out of Somerset, they have gone through 2 FDA inspections and again, as a new facility, we do not know what you do not know. We are very pleased that we were able to sail through the two inspections. We got 14 FDA approvals in the year we made 8 new product launches, a number of launches in the last quarter. So are looking forward to getting the benefit of the impact of Q4 launches as well as new launches from



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Somerset in fiscal year 18. So with the product launches out of India as well as Somerset, we are working hard to try to offset the erosion that we are going to see in our base business and we will try our best and we are confronted with the challenge with WBAD EconDisc pressure, we will again try our best to gain volume to offset erosion in pricing.

Prakash Agarwal: So with those efforts, would that mean that growing early double digit growth rates are possible?

Vinita Gupta: In the near term like I said fiscal year 18 will be a challenge. I wish I could say that we will be able to do a double-digit growth in fiscal year 18, I think we will definitely offset all of the price erosion in our base business ex Fortamet, Glumetza with the new product launches and we will try our best to offset Glumetza and Fortamet as well.

Prakash Agarwal: And lastly some color on Tamiflu, it was expected by Feb-March, it has been kind of delayed and also on Tamiflu suspension and some color on Ranexa and Renagel. Thank you.

Nilesh Gupta: We were hit by one of the CRLs having trouble on the Tamiflu products, the Temmler CRL. So, we had to repeat the studies and we have filed those. I think as in the next 6 months, we expect to be able to launch both those products. Ranexa is planned for launch in FY19 and that is one of the biggest products for FY19 and the Sevelamer/Colesevelam products have been allusive almost for the industry, but certainly for us and I see them really as late FY19 opportunities. We have had CRLs that we are working to respond. It will take pretty much the best part of this year to respond to the CRLs which we need to make API again, finished product again, file it and I think those will be late FY19 opportunities.

Prashant Poddar: I am Prashant from Abu Dhabi Investment Authority. You did mention about pricing pressures incrementally in Japan as well that the government is contemplating. Can you elaborate that a bit?

Nilesh Gupta: We have Fabrice, our head of APAC here, so maybe he can answer.

Fabrice Egros: Good evening, ladies and gentlemen. There are a number of proposals from the Japanese government in order to maintain the total healthcare budget under control to essentially go across the board for annual price cut instead of price cut every 2 years. This measure is not yet decided under voting, the answer will be known in October.

Nilesh Gupta: When he said annual price cut ticks in, then that will kick in from FY19.

Prashant Poddar: And just said as an extension, are there levers in that market that we have to maintain or at least help margin in case that happens.

Nilesh Gupta: So, we are seeing pretty structural changes as far as the Japan generic market is concerned and based on that, we have been moving to hybrid and then specialty strategy in Japan. This is a



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common way and across all the developed markets that we see. So in Japan if you see last year, we acquired Shionogi portfolio that has significantly shot up the topline and the bottomline of that business. We also entered into the agreement on Quetiapine Extended Release that is pure specialty as far as Japan is concerned. So I think we are going to keep focusing on the generics, focus on high value generics and then build more of a hybrid and specialty strategy. We are doing that in Japan, we are certainly doing that in the US and we are doing that in Western Europe as well.

Ramesh Swaminathan: I would also add to that, we are also working on several operational excellence measures. First would be in terms of procurement, you obviously can look at lowering cost. The margins that the vendors are able to get in Japan is something which is astounding. So we could work on that. The second is of course we would try to pass on part of the value erosion to the channel partners also. So, we will work on those avenues to minimize the impact on our bottomline.

Prashant Poddar: One last one on acquisition, if you can help us understand what is the acquisition strategy and what are the focus areas in terms of acquisition at this point of time?

Vinita Gupta: Focus areas are specialty, we had also mentioned that in the last few quarters that we have been able to get into geographies that we wanted to be in. We have been able to gain technology capabilities with GAVIS, with Nanomi into areas that complement ours. The major area of focus for us going forward is specialty. The therapeutic areas that we are focused on right now are Women's Health, Pediatrics and CNS. In the US, you have seen us get into Women's Health last year with Methergine. We are looking to build upon it. We had a good run rate right now with Methergine, but we would like to really add to the portfolio. On the pediatric front, we have the legacy portfolio of Suprax as well as InspiraChamber. We are looking to add through both pipeline as well as acquisition and on the CNS front, Neurology in particular we are looking to acquire products across US, Europe as well as Japan.

Cheenu Gupta : This is Cheenu from Tata AIA Life Insurance. You spoke about building up your specialty and biosimilars business, could you give us an idea about the kind of costs that you will have to incur maybe in terms of R&D spend or adding to your salesforce?

Vinita Gupta: So on the specialty front in the near term, majority of the sales would be through partnering as well as acquisition. And the way we are looking at it is that we want to acquire multiple product assets hopefully in the \$100-\$200 million range that can help us build into the therapeutic areas that we have chosen. And it would also require commercial built, but now that we have a Women's Health commercial presence in the US, we have got Pediatric presence in the US, we have got CNS presence in Japan, we will build CNS presence in Europe, we will be able to leverage that commercial presence across broader portfolio products and get operational leverage on the specialty front. On the biosimilars front, majority of our effort is going to be pipeline. In the near term, we are investing a percentage of our R&D spend into biosimilars and it is selective few products. We are not taking a large exposure onto biosimilars because the



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biosimilars market has yet to evolve. When we look at the US market, if you look at the European market, there have been some successes but also a lot of challenges. So we have chosen a few products where we think we have room to play, we can make a difference. First program is Etanercept that we have funded through clinical development, it is progressing very well through clinical development right now. We hope to file it in Europe later this year and into US next year and behind Etanercept, we have Pegfilgrastim and Ranibizumab. Again programs where we feel like we can be one of few in the market and therefore hope to get a reasonable share and good margin. But majority of the efforts on the biosimilars front in the near term is pipeline and R&D.

Cheenu Gupta: And just on the specialty, what phase of molecules would you look at because of the tradeoff between risk and the investments?

Vinita Gupta: We started with wanting products that are already commercialized in the market, but those are far and few and they are well priced. There is not much value to build upon it. We look for growth opportunities and at this time we are looking at phase 2 completed onwards. If it is a proof of concept completed assets to programs that are in phase 3 developments and to phase 3 completed assets. In addition to both, wherever we can get the opportunity to bolt on existing molecules, existing commercialized products in the therapeutic areas of our focus.

Neha Manpuria: This is Neha from JP Morgan. Vinita, what is the progress on our Advair filing?

Vinita Gupta: So, we have made good progress. We have developed, we have taken exhibit batches of the product. We are in PK development right now based on the feedback that we got through the Mylan CRL as well as Hikma. Our scientists picked up that it would benefit us to do some additional PK work before we go into the PD study. So we decided to do some additional PK work at this point. So, we expect to get into the clinic later this year and we likely will file early next fiscal year for Advair, assuming success all along the way. As you know earlier in this year, we filed our first complex inhalation product. We have filed Tobramycin which we have got approved already for cycle approval. We have to launch it this year, but with the MDI as Dr. Sharma said, Albuterol, we filed in January of this year and Tiotropium DPI, we are making really good progress. We completed PK development and have initiated PD study at this point. So progressing that well and subject to successful completion of the PD study, we would like to file this fiscal year.

Neha Manpuria: And given the headwinds that you mentioned on the US business particularly for Glumetza and Fortamet, we did 27% margins this year, how should we look at margins next year if business erosion and erosion in Glumetza and Fortamet, initially I think we mentioned 25% to 28% as a margin range over a medium term.

Ramesh Swaminathan: I will take that question. As you realized, it is actually a function of three things, the kind of products that will bring to the market. Second is our focus on the operational excellence measures and third is our R&D spends. Speaking about the last, we would like to contain it same



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levels this year. On the operational excellence front, we have been working on this several ways of excellence that we have been proceeding at the factory level in terms of procurement both in India and abroad and so on. So all of these have actually paid a lot of dividends, during the course of the year and we expect further dividends in the future as well. And of course on the products front, our pipeline is very strong. But that said, next year is indeed going to be muted year. So we think we have been able to maintain margins between 26% and 28%, but going forward we expect to increase on that.

Neha Manpuria: And this would be on what R&D spend sir, if any?

Ramesh Swaminathan: The same level at this year.

Neha Manpuria: 13.5%?

Ramesh Swaminathan: 13.5%.

Sameer Baisiwala: Sameer from Morgan Stanley. Just quick question on your fiscal 18 target. If I remember correctly, it was \$3.5 billion on topline and for Gavis, it was \$250 million, so any updates on this?

Vinita Gupta: So with all the structural changes that we have experienced in the last year and expect going forward with the pricing pressure that we have seen, additional pricing pressure that we expect, mean FDA approvals, yes have improved but still on material products like Colesevelam/Sevelamer. We have struggled to get FDA approval, and not only us, the industry has. So with the lack of meaningful product approvals, we expect that the next year like we said the growth is going to be muted, but fiscal year 19 onwards we should start seeing a good double digit growth. We expect to be at 3.5 billion and beyond by fiscal year 20 as we unfold our complex generic portfolio, we expect our inhalation product to start kicking in fiscal year 20, expect albuterol to come to market and then Spiriva, the year after. So we would like to be at a place where we could get to our aspirational goal in the next year, but given all the changes in the market place, we expect that we will really get there in the next 2 to 3 years' timeframe.

Rakesh Jhunjunwala: So 19-20 that is for the entire company?

Vinita Gupta: That is right.

Rakesh Jhunjunwala: Another question I had is about the Japanese, you said they are cutting prices, but are they increasing volumes of generics?

Nilesh Gupta: They have been doing that in the past and I think what we are seeing now is that the government seems to be happy with the amount of generic substitution that there is. They also want to limit the competitors that they are, they have actually signaled that they will really like to see five



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generic competitors in every product. We have as many as 30 competitors that come up at times. We are number 6 in Japan and I think we have a really good chance to be part of that five and to have a meaningful portion of the share as well, but we are seeing that the generic growth rate is coming down in Japan.

Rakesh Jhunjhunwala: It does not make common sense, but that is a reality. What I wanted to ask very important is with the price erosions and fall in margins, how do you see the competitive strategic position of the industry is? Today, valuations are down. So would you not think there has been lot of consolidation on the buying side, would not there be extreme consolidation on the selling side also?

Vinita Gupta: Now would expect that very much, lot of companies will struggle to meet the requirements the need of the day and I would expect to see additional consolidation on the supply side.

Rakesh Jhunjhunwala: We had acquired a Polish company or a product from Polish company got a delivery of the Celon

Vinita Gupta: Celon. We had not acquired the company.

Rakesh Jhunjhunwala: You acquired the company or rights?

Vinita Gupta: We got right to the device from Celon.

Rakesh Jhunjhunwala: Of which country?

Ramesh Swaminathan: For US.

Rakesh Jhunjhunwala: You are trying for which country.

Vinita Gupta: For US, Canada, Latin America, South Africa, but it is primarily US.

Rakesh Jhunjhunwala: But it is already approved in Europe.

Vinita Gupta: Yes.

Rakesh Jhunjhunwala: So therefore approval in America should not be so difficult.

Vinita Gupta: It is a first company that got approval for in Advair generic in the developed markets. So we would expect them to be placed better, and hence we are placed better. We have been working with them for the last 2 years now to get them up to USFDA standards and have come a really long way.

Rakesh Jhunjhunwala: What is the market size of Advair?



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- Vinita Gupta:** \$8 billion.
- Rakesh Jhunjunwala:** The European regulator has approved, but the American regulator has different rules.
- Vinita Gupta:** That is right. We expect also in the US at least for the new administration is saying right now, they are going to bring lot of regulatory reforms, the new FDA commissioner, Scott Gottlieb is also saying the same thing that they are going to work with the FDA to try to get them to work with the industry on better pathways, easier pathways to get products approved to accelerate generics into the market.
- Rakesh Jhunjunwala:** And Advair is already a generic?
- Vinita Gupta:** It is not generic.
- Rakesh Jhunjunwala:** No, it is off-patent.
- Vinita Gupta:** It is going to be off-patent this year. 2016 actually, it is off-patent.
- Rakesh Jhunjunwala:** But nobody has launched?
- Vinita Gupta:** Nobody has launched. Nobody is approved.
- Rakesh Jhunjunwala:** GSK product?
- Vinita Gupta:** GSK product.
- Rakesh Jhunjunwala:** That will hit billions...
- Vinita Gupta:** Yes.
- Rakesh Jhunjunwala:** Some other products like this?
- Vinita Gupta:** So, it is all about exclusive products. To be honest, while we are saying that generic we are going through a consolidation phase that the market growth is shrinking, if you look at our history over the last 7-8 years, we have constantly expanded our margins and how we expanded it, through exclusive products. From where we started back in 2005, started with 40%-50% margins and are consistent basis evolving our pipeline and portfolio with products that had limited number of competitors helped us expand margins and we have seen that all the way till last year. So I do not see that basic fundamentals change. Yes, compared to the high base of Glumetza, Fortamet, we have a challenge in the near term, but just given our investments into our pipeline with multiple first-to-files, we have in the next 5 years 14 first-of-files with \$2.5 billion in revenues that we expect to bring to market. We have these complex generics like the inhalation products. After that, we have the complex injectables and then we have biosimilars coming. So with the



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additional complexity in all of these areas and the challenges and barriers while I think will be challenging for us as well, we are not going to be successful with everything. We are going to have a better pipeline going forward. We have a better pipeline and we have built a better pipeline over the last few years that has helped us grow our margin. As I look at the next three years to five years we will be able to build our margins. The basic fundamental in the market has not changed, I mean generics are here to stay. When with all the cost containment pressure on government whether in US, Europe, Japan there is going to be more and more utilization of generics as I see it.

Rakesh Jhunjunwala: How many other people are working on this?

Vinita Gupta: You have Mylan working on it, Hikma working on both expected approvals this year, both have challenges. We know the Sandoz has been working on it for many-many years and Teva is working on it.

Rakesh Jhunjunwala: A lot of people trying?

Vinita Gupta: A lot of people trying.

Rakesh Jhunjunwala: The other question, what was the Gavis revenue in the current year. What do we expect?

Vinita Gupta: So, we are one year behind in Gavis. As we brought the company into Lupin and there were a few surprises for us and we integrated the company well over the last 12 months. The last quarter in particular as I mentioned we have seen a ramp-up of material products like Methergine is a material product out of Somerset that we have ramped-up. We have seen multiple product approvals in the last quarter; have launched a few, and multiple others that we are working on launching. So, we expect to be in that \$200 million plus range in the coming year out of Somerset.

Rakesh Jhunjunwala: You have done an agreement with a Japanese company for a biosimilar where we are providing the technology and they are doing the trials.

Vinita Gupta: We are doing the trials along with them.

Rakesh Jhunjunwala: In Japan?

Vinita Gupta: In Europe and Japan.

Rakesh Jhunjunwala: What is the product?

Vinita Gupta: What is that product, it is Etanercept, Enbrel brand.

Rakesh Jhunjunwala: Then why do you need them? If both of you were doing the trials then why do you need them?



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- Dr. Kamal K. Sharma:** It is a joint development, so we are actually sharing the cost with them.
- Rakesh Jhunjunwala:** For the trials.
- Dr. Kamal K. Sharma:** For the trials.
- Rakesh Jhunjunwala:** And marketing everybody will have right?
- Dr. Kamal K. Sharma:** No, we will have our own...
- Rakesh Jhunjunwala:** Both companies will have the right?
- Dr. Kamal K. Sharma:** Yes, we have right in Japan as well and I think this is a joint development where we are sharing the development cost because as somebody asked in the audience for biosimilars for each geography you incur almost like anything between \$40 million to \$60 million for clinical development and this being our first product we did not want to take on the entire risk, so we have shared with them.
- Rakesh Jhunjunwala:** When do you hope to launch it?
- Nilesh Gupta:** We plan to file in Europe in FY 2019.
- Rakesh Jhunjunwala:** What is the size of the product?
- Nilesh Gupta:** Actually we plan to file this year and we plan to launch in next year.
- Dr. Kamal K. Sharma:** It is actually totally in cost \$8 billion product, so it is a huge product actually.
- Rakesh Jhunjunwala:** And Europe and Japan also....
- Vinita Gupta:** US is the largest.
- Nilesh Gupta:** Japan is about \$700 million,.
- Rakesh Jhunjunwala:** And Europe also build large product and for cancer you are not launching in America?
- Vinita Gupta:** No, we will file it in America as well.
- Dr. Kamal K. Sharma:** America there is a patent which is not there in Europe and Japan, so Sandoz I think has challenged that patent?



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- Rakesh Jhunjhunwala:** Till when?
- Vinita Gupta:** 2028, but it has been challenged.
- Participant:** I have two questions, one can you just talk about the Indian market and the risk of recent government actions that means can the growth go down below 12% whatever is going on? And second question is as you go after the specialty products, Phase-III, Phase-II, does the R&D cost then go up from this 13.5%.?
- Nilesh Gupta:** We have Rajiv, our Head of India Region, so I will let him answer the first question.
- Rajeev Sibal:** In the last few years also one of the market which is very stable in growth is India. Indian market has grown in the last few years also around 12% to 13% and we see very surely that in the next few years also if you look at the IMS prognosis report also they have also projected Indian growth at close to 12% for the next five years. So, I do not see any challenge as far as next five years growth of Indian market is concerned and as far as Lupin is concerned, we are placed very-very comfortably as far as our portfolio is concerned and I am sure, the way we have grown better than the market in the previous year, I am sure we will continue that pace as well in the future also.
- Vinita Gupta:** In terms of the investments to build the specialty pipeline we certainly recognize that as we take on Phase-II, Phase-III assets we are going to have additional expenditure. But we have decided that we are going to be able to manage it within the current level of spends over the next two years. So we have been prioritizing our pipeline on annual basis to look at where is the best return for our investment and have been working on creating room for specialty. So, we have started specialty pipeline in a small way in the last couple of years. We have six products in development right now. We have ADHD films that we are developing in partnership with MonoSol in the US for the Pediatric market. We have two Methergine line extensions that we are developing as part of our specialty pipeline. We have a derm product that we are developing as part of our specialty pipeline. We are investing into mexiletine as Dr. Sharma was mentioning in Europe with a Temmler acquisition we got rights to a product for Myotonia in Neurology, it is potentially an orphan drug in Europe we have been developing it over the last year and half and are planning to file it in the next quarter in Europe. So, we have started in a small way in building our pipeline but hope to be able to create more room in our R&D spends for specialty.
- Participant:** You did mention about consolidation of distribution in US continuing the announcement last week. So, the margins that you have indicated 26% to 28% that will be able to withstand that as well if at all?
- Ramesh Swaminathan:** We have not done a stress test on it but we would think it is between 26% and 28% because it is too early.



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- Vinita Gupta:** Well, and we have multiple levers as Ramesh mentioned earlier, we are doing our best at looking at how we can leverage our existing portfolio near-term pipeline but also the operational lines looking at more efficiency out of our operational expenditure to be able to get to that kind of EBITDA.
- Participant:** What is the R&D quantum expected in the next year?
- Nilesh Gupta:** Yes, we see it pretty flat at the current level for the next two years as an absolute amount.
- Participant:** What are the prospects of R&D pipeline?
- Nilesh Gupta:** Raj is here as well but let me start that answer. We have our lead product in Phase-II in Europe right now the results of which should be available by the end of this financial year. So, I think next year we will actually have Phase-II results for three of our programs that would be available and it think that would be a great point to take stock of our NCE.
- Participant:** Since you are trying to build a specialty portfolio, wouldn't your own infrastructure, be able to support the promotion?
- Nilesh Gupta:** No, I think for all these three products the intent would be to license out after Phase-II, so it will be out of those three.
- Vinita Gupta:** No, we will license it out and try to build our specialty portfolio. We will take a look but you know out of the three programs there is may be one – the Endocrinology is one that potentially can fit a specialty model but otherwise oncology and Rheumatoid Arthritis are very large categories and you need very strong commercial muscle to be able to compete and succeed in those areas, so it would make sense for us to partner with a company that is established and if we are successful with these programs.
- Nilesh Gupta:** I think that is what we are using to build our specialty pipeline so that is where for example on the Methergine line extension we are using some of the technologies that we have. There are questions in the back there?
- Prakash Agarwal:** Thanks again. Just trying to understand the comment you made on fiscal 2019 looking at some double-digit growth. Just listen to the fact that Sevelamer/Colesevelam looking at late fiscal 2019, and then you talked about the specialty still being under development which are entering clinics or being filed in the next two years. Very broad level if you could highlight what will drive the fiscal 2019 double-digit growth that would be very useful. Thank you.
- Nilesh Gupta:** Sure. Maybe I can start then Vinita you can add. So, we have a huge pipeline pending with the FDA, so I think there is a lot of small to mid-level products that will come, you will see at least 30 of them in FY 2018, you will see even more in FY 2019. Again, the opportunity is going



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down with time but you will see a lot of the dermatology products coming to market in that horizon. We have at least three exclusive First-to-Files that will come to market in FY 2019 we talked about Ranexa, Minocycline ER is an FY 2019 opportunity as well, MoviPrep, a part of Somerset is a FY 2019 opportunity as well and that is just the exclusive First-to-File. I think there are a lot more products.

Vinita Gupta:

Yes, Nilesh covered majority of it, like he said that multiple First-to-Files. By FY 2019 we will have \$1.2 billion worth of First-to-File, Exclusive First-to-Files that we bring to market the biggest out of it will be Ranexa followed by Minocycline ER and MoviPrep. This year itself we see a few products like Lanthanum that three companies filed. We know that our competitors have had trouble and it looks like we are close to approval, so we will have a nice opportunity with it, I mean that is through a partnership with Natco. Other large material products, Levothyroxine, it is not First-to-File but very large molecule, where we have been successful in getting bioequivalent product and filed to the FDA, we expect to bring it to the market in fiscal year 2019. In addition to that, out of Somerset, by fiscal year 2019, we expect the controlled substances to become a big part of our portfolio. There are number of products that we are building upon right now in controlled substances. We just launched in the last couple of months, Hydrocodone APAP, and with our first smaller strength version we got 20% of share which is what we are used to getting and with the controlled substances you have this chicken and egg story. You have to be able to get share from the customer to be able to get quota and you would not get quota until you have share. So, we have been able to work now with our customers as well as DEA to be able to really get our commitment from our customer and convince the DEA to be able to give us quota and as we work through this portfolio in fiscal year 2018 we expect controlled substances to be a good part of our revenue build out of Somerset.

Prakash Agarwal:

Thank you for that. And just wanted some clarification on this Indore facility which got six observations in the May inspection. Could you give us some color on what kind of observations are these?

Nilesh Gupta:

We feel that we are going to be able to address these observations. None of them obviously go in the direction of data integrity, like a couple of them are repeat observation from the Goa last audit where we had three observations. I do not see the situation escalating and I feel that we will be able to address it pretty comprehensively.

Prakash Agarwal:

Thanks and lastly one for Ramesh. Just trying to understand the FOREX loss, so if we see the last four quarters, other income is about INR 2.5 billion and if you see this quarter it is about INR 453 million. So, what I understand is all the FOREX gain has been nullified first to look at the fiscal 2017 other income of INR 1 billion, is that right understanding?

Ramesh Swaminathan:

Total FOREX loss for this quarter is about Rs. 170 crores. It is hidden across these three lines. I am not able to relate to a lot of those figures that you are speaking about let me take it offline but that is the major jump during the quarter.



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- Prakash Agarwal:** And this gets nullified for the last nine months of FOREX gain when you account for full year accounting?
- Ramesh Swaminathan:** Yes, generally we do not have too much profits for this year, that is true.
- Prakash Agarwal:** Okay. So, because I was looking at fiscal 2016.
- Ramesh Swaminathan:** There is a loss for sure.
- Krishnendu:** Just one very simple question. Trump cut \$600 odd billion from the Medicaid so how does it affect us I am talking about Lupin does it affect us at all generic-generic and the specialty going ahead do we see pressures in that front Vinita if you can just elaborate on that? Thank you.
- Vinita Gupta:** It is very early to tell. This just happened yesterday and we are still trying to find out the details of what the administration is proposing. We have a small component of Medicaid business, so we do not expect to have a major impact. I think our Head of the US Business, Paul McGarty is here. So, let him elaborate in it further.
- Nilesh Gupta:** He can answer all questions on Trump for you guys.
- Paul McGarty:** I should have asked a few minutes ago, if that is the question. But Yes, I spent this morning reading the proposal that you just talked about and I can say after reading it several times that it's any clear to me than it is to anyone else out there, I am just trying to analyze it at this point and it certainly got a long way to go. I would say our business in the US, may be 6% or 7% of our business, is Medicaid and I don't think anybody really looks at Medicaid in the United States as really that component of business that you really have to see to be developed on new products or a new area it is certainly not the one that is the highest value offer, so it should not have any impact on us for sure.
- Rakesh Jhunjunwala:** Are the consolidators passing the price discounts they get, on the customers?
- Vinita Gupta:** They are being challenged now by the payers to try to pass on more to the payers. I mean so far, they have been pocketing it.
- Vinita Gupta:** Yes, but now they are being challenged.
- Rakesh Jhunjunwala:** The American Competition Commission equivalent they are allowing this kind of consolidation? The generic industry is not complaining?
- Vinita Gupta:** You remember these are our customers. So, it is a double edged sword and Mylan complained when they had the EpiPen issue Heather Bresch was at Capitol Hill complaining about the PBM, it did not help her or Mylan.



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- Rakesh Jhunjhunwala:** Not Capitol Hill, there will be independent trade commission that will decide no?
- Vinita Gupta:** You know in the last couple of months I have spent a lot of time in DC in the capital with senators and congressmen and every time you go to someone they said, 'please explain to me how this works.' I mean our industry is so complex in terms of how the WAC works and reimbursement price and the contract price that we earn from selling to the customers.
- Rakesh Jhunjhunwala:** It is just a common sense that in any industry, it is not a Senator to decide, there is a federal trade commission they must be deciding, would they let anybody become 40% of an industry.
- Vinita Gupta:** You are talking about the consolidation.
- Rakesh Jhunjhunwala:** Yes.
- Vinita Gupta:** So the challenge there is I mean if you look at the impact of that consolidation what does it do? As long as our customers are passing the benefit to the patients and the payers, so that is the big question mark. As long as they do that the consolidation is going to really give them the leverage to buy the lower cost, so potentially to bring cost down overall. So, to fight that is very difficult and this is really what they have done is created a buying group, it is a group purchasing organization like buying groups, it is not like two payers coming together
- Dr Kamal Sharma:** But it would be fair to say that once the payers come together then they will sell out their gains to the customer.
- Vinita Gupta:** I mean the large payer merger was blocked by FTC.
- Rakesh Jhunjhunwala:** I mean competition is competition, if you and Mylan collaborate, they will take you to jail. They are also buyers and if they collaborate that is allowed.
- Vinita Gupta:** The question is what is the impact of that competition? In this case, it is the impact is lowering price, potentially.
- Participant:** Just a follow-up, I am think out loud, if Amazon comes in what happens and for my knowledge when the target action date for Pro Air?
- Vinita Gupta:** So, the target action date for Pro Air is September of this year and I think Amazon can be disruptive.
- Participant:** So, what do you think could happen if Amazon comes in?
- Vinita Gupta:** I mean if they are really able to create a new channel in the market place I think it will be great to have more competition from a customer standpoint and they can truly be disruptive. I think early in their evolution of this whole model I mean they have got someone from the payers' side



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from the Blue Cross - Blue Shield to come and lead the whole effort and they are trying to put the whole model together but we would explore that as well. I mean we will explore working with an Amazon to try to bring generics to market.

Rakesh Jhunjhunwala: Most of the American medicines are made from an insurance company. So, what do I get to buy from Amazon.

Vinita Gupta: Yes, but it is just an additional channel that will come into the market, you will be with a new customer

Rakesh Jhunjhunwala: It will give you an advantage? You will have additional buyer.

Vinita Gupta: Yes.

Rakesh Jhunjhunwala: Amazon to succeed there is no real benefit of price to the customer.

Vinita Gupta: Amazon might do that. I mean their whole model has been value to the customer, right? They price match, they guarantee of lowest price to the customer. So, maybe they will tie-up with the insurance group and say we will give you the lowest price. We yet to unfold but I think it is worth, I think it is an interesting play.

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