



May 23, 2019

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**National Stock Exchange of India Limited**  
Exchange Plaza,  
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**Mumbai - 400 051.**

*Dear Sirs,*

**Annual Investor Meet FY 2018-19 Conference Call.**

Pursuant to Regulation 30(2) read with Schedule III Part A(15) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, enclosed is a copy of the Transcript of the Annual Investor Meet FY 2018-19 Conference Call on Wednesday, May 15, 2019 at Mumbai.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,  
For LUPIN LIMITED

*R. V. Satam*  
*ACS 11973*  
**R. V. SATAM**  
**COMPANY SECRETARY**



Encl.: a/a

LUPIN LIMITED

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## “Lupin Limited Annual Investor Meet FY 2018-19 Conference Call”

May 15, 2019



**MANAGEMENT:**

**DR. KAMAL SHARMA – VICE CHAIRMAN, LUPIN LIMITED**  
**MS. VINITA GUPTA – CEO, LUPIN LIMITED**  
**MR. NILESH GUPTA –MD, LUPIN LIMITED**  
**MR. RICHARD ZAHN – INDEPENDENT DIRECTOR, LUPIN LIMITED**  
**DR. K. U. MADA – INDEPENDENT DIRECTOR, LUPIN LIMITED**  
**MR. ALOK SONIG – HEAD OF US GENERICS, GLOBAL HEAD - GENERICS R&D & BIOSIMILARS, LUPIN LIMITED**  
**MR. NARESH GUPTA – HEAD, API PLUS, LUPIN LIMITED**  
**MR. DEBABRATA CHAKRAVORTY – HEAD, PROCUREMENT AND SUPPLY CHAIN, LUPIN LIMITED**  
**MR. SUNIL MAKHARIA – PRESIDENT FINANCE, LUPIN LIMITED**  
**DR. SOFIA MUMTAZ – PRESIDENT PIPELINE MANAGEMENT AND LEGAL, HEAD OF GOVERNMENT AFFAIRS IN THE US AND HEAD OF CANADA, LUPIN LIMITED**  
**MR. YASHWANT MAHADIK – HEAD OF GLOBAL HR, LUPIN LIMITED**  
**MR. RAJIV PILLAI – SR. VICE PRESIDENT (CORPORATE PLANNING), LUPIN LIMITED**  
**MR. ARVIND BOTHRA – HEAD OF INVESTOR RELATIONS AND CORPORATE M&A, LUPIN LIMITED**



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**Moderator:** Ladies and gentlemen, good day and welcome to the Lupin Limited Annual Investor Communication FY 2018-19 Conference Call. As a reminder, all participant lines will be in the listen-only mode. Should you need assistance during the conference call, please signal an operator by pressing \* then 0 on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Lupin management. Thank you and over to you.

**Arvind Bothra:** Good evening everyone. Welcome everyone to Lupin Annual Investor Meet 2019. I will request Dr. Kamal Sharma to start off the presentation and welcome you all.

**Dr. Kamal Sharma:** Good evening everyone. It is a pleasure to welcome you to today's Annual Investors Meet. Before I hand over to Vinita and Nilesh to walk you through the strategic drivers of the business and the operational performance, just to set the context, I would like to say that by now you have seen the results. It has been a very turbulent time for the business, however if you see the progress of the company from Q1 to Q4, there has been a steady progress as you would have noticed. Most notably in our major markets like the US where you see a sequential growth of 23%, despite all the pressures on prices and general dynamics of the business. The team has put up a good show and what is heartening is that this is something that we are all committed to take forward.

India business continues to be robust, we have grown by 12% over last year. There are some other markets of RoW which have done very well like South Africa and Australia. There are pressures on some markets. But that is part of life and part of the journey and we are doing everything to see how we can improve there. It is heartening to see that the quality of our business is steadily improving. EBITDA margin in Q4FY19 stood at 22.2% and for the year 2019 it was at 19.8% to be very precise. From where we began the year and where we are today, it's been a steady rise. Also, there has been a steady progress on complex generics, biosimilars and specialty area – details on the



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same will be shared by Vinita. With that, I would like to say that the team remains committed to produce all-round better results, and we are all committed to drive productivity and efficiency across the company. Thank you very much. I now hand over to Vinita and Nilesh to walk you through the strategic drivers of the business and the operational performance

**Vinita Gupta:**

Thank you, KKS. Good evening everyone. It is a pleasure to see you all. We always look forward to meeting you once a year around our annual results and sharing with you our perspectives on the year gone by, as well as how we look at the future prospects.

Before I do that, I would like to introduce some new members of our team to you. Sitting right in front is Alok Sonig. Alok has joined us as the Head of US Generics - integrating R&D through commercialization, as well as heading Global Biosimilars and has infused new energy in our Generics team at the right time. Right next to him, is Naresh Gupta, the Head of API business. All of you know that the API business has done extremely well this past year with 20% plus growth. It has been Naresh and his team's passion that has gotten us so far, in a company that is so focused on building the finished dosage business. He has done a wonderful job leading the team to grow the API business. Next to Naresh is Sofia Mumtaz. Sofia has got one of the most complex set of responsibilities. She is the Global Legal Head, Head of Pipeline, Head of Government Affairs in the US and Head of Canada and plays a material role in the company both in terms of creating opportunities as well as mitigating challenges for the organization. Next to Sofia is Yash Mahadik, who you haven't met in the past. He is the Global HR Head and again it has been one year since he has joined. He has made a material difference to the organization in a short period of time that he has been with the company and will really help us as we build our talent for the future to grow our people along with the aspirations that we have for the organization. Next to Yash is Debu Chakravorty. Debu again has multiple critical sets of responsibilities in the organization. Right now, Debu leads both procurement as well as supply chain and is a big strength in terms of our focus on cost optimization for the



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organization. We have Rajiv Pillai, Head of Business Finance and Arvind Bothra, whom you all know very well, Head of Investor Relation and M&A. We have Sunil Makharia – President (Finance) as well. You know that we don't have a CFO at present and have been conducting a search. We are making really good progress, but in the meantime the strength that we have in the finance team has really helped us get very close to the business, understand the business even better and determine how to drive our business forward to drive profitable growth in future years.

I will briefly walk you through how we look at the market, in particular the markets that are relevant to us. As KKS said, this has been a turnaround year for the organization. We certainly look at it like that. Q1 started on a very rough note for us, in Q2 our business stabilized, in Q3 we did better particularly in the US and in Q4 - we closed on a very strong note both in terms of revenue as well as profitability, including EBITDA margins. While we have the exclusivity of Ranexa that was a good contributor to Q4, we have other underlying growth factors as well. We have gained confidence over the years on our base generics business to drive growth. Likewise, we have made material progress on our strategic growth drivers whether it is complex generics or specialty that we would like to share with you; and how do we look at these areas to help us drive our growth objective in the mid to long term.

Starting with the US generics market which has been the largest part of our business and as we look at the future, will continue to be the largest part of our business going forward. We have seen a very encouraging trend in the last year. Over the last four quarters, we saw multiple indicators that basically gave us the confidence that the generic business in the US is stabilizing. When you look at lead indicators like ANDA submissions or product discontinuations, it is very heartening to see that companies are really driving towards profitable growth. We saw that price erosion in the US which was in the double digits for couple of years, has now abated somewhat. It is a really heartening trend that we see in the US generic business and we believe that



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it is here to stay. The conversations that we have with our customers today are very different from what we used to have couple of years ago. They are cognizant of the fact that for a healthy generic industry, manufacturers have to make a decent margin and it's great to have that reality set in. When we look at the future of US generics, we believe it is set for growth; 1) on the stabilizing base business, 2) on a number of opportunities in terms of products going off patent over the next 5 years. When you look at the next 5 years, \$90 plus billion worth of product go off patent and increasing number of complex generics are available to genericize over the next few years.

When you look at the contribution or participation of the Indian companies in the US, it's a pretty healthy sign. The Indian companies have gained share in the last 5 years - from the high 20's to ~45% market share in the US currently. We are a material part of the US healthcare solution. Among all the concerns on drug spend, generics is a solution for drug spends despite all the pricing issues and the negative publicity that generics get – but, generics are in fact the solution to lower healthcare costs.

Switching to the Indian pharma market, we are very bullish on the Indian market. We had disruptions in FY18 - namely GST, demonetization, ban on fixed dose combinations because of which growth came down a little bit, but this past year we have seen India rebound with double digit growth. As we look at the future, we believe that the double-digit growth is here to stay. When you look at the therapeutic areas that are driving this growth, the chronic therapeutic areas are growing faster than acute. And as you look at the chronic therapeutic areas, the top three, antidiabetic, respiratory and cardiac are also our top three therapeutic areas. Lupin is number 2 in respiratory, number 3 in diabetes as well as cardiology. These three therapeutic areas account for 55% of our revenues. Therefore, you see Lupin is able to grow at a faster pace than the Indian pharmaceutical market. As we look at the next 3-5 years, we believe the Indian pharma market will grow 10% plus. The government in India has come up with multiple measures, Jan Aushadhi trying to get more generic, generic utilization to bring access to low



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cost medicine, but we haven't seen a material shift in the share of the branded generic segment, it is still close to 95% and we don't see that trend changing anytime soon.

The US and India are two-thirds of our revenues and a bigger part of our profit. But as we look at our third largest market, Japan - the market has been fairly flat over the last 5 years. However, within the Japanese pharma industry, the generics market has grown driven by the measures that the government had put in place to drive generic utilization.

Over the last few quarters, we have shared with you all, that pricing pressures are here to stay in Japan. We have worked hard to improve our margins in Japan through back-ending products into India where we get better end-to-end margins. Additionally, we have right sized our infrastructure in Japan based on the current market needs to really help in the interim. In the mid to long term, we believe that our focus in complex generics and specialty much like the US will also drive growth in Japan. Etanercept, in particular will drive growth in Japan for us in the near term.

When you look at our other markets, Germany, UK, Brazil, Mexico all the way to South Africa, the growth has been low or flat in most of these markets over the past few years. In few of these markets there has been double digit growth but because of currency fluctuations, the political instability in markets like in Mexico, Brazil, which had elections last year and the new President brought about significant pressures on the currency, you see low US\$ growth in these markets. Our focus on these markets and the other developed markets of Europe, Australia, is to scale organically and make these businesses self-sustainable. Majority of these countries are already self-sustaining. Brazil is relatively speaking newer into our mix and we have invested recently but we are working hard to get Brazil also to a level that it can sustain its own growth.



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Now diving deeper into the areas of our focus, complex generics and how do we look at the complex generic opportunities. As we look at the products going off patent, we look at the opportunities on the generic front, a larger percentage of the dollars are now in complex generics, whether it is injectables, biosimilars, devices or others. Likewise, price erosion on the complex generic front has been much lower than the oral solid front. Price erosion in injectables have been relatively been flat. Likewise, other dosage forms where the competition is limited have been relatively flat. Therefore, the move to try to really build a portfolio of complex generics.

As we dive deeper into areas of our focus, inhalation products. This year has been a material year in terms of the evolution of inhalation products in the US. We have had very good adoption on the inhalation products with the first real approval of a dry powder inhaler, for Advair in the US. Now, this is not our product, it is our competitor's, but it is very heartening to see the FDA actually approved a DPI. It gives us the confidence that our pipeline of MDI and DPI products is approvable in the future and will help us build our complex generic business going forward. Also going back to Advair, when you look at the market conversion, 45% of the market has converted to the generic or authorized generic. We have seen a good level of substitution in a couple of months. When you look at Albuterol, now this is a little bit different than Advair of course. Albuterol does not have a true generic yet, we hope to be the first real generic in the market place, but the brand company GSK, Teva as well as lately Merck - all launched authorized generics. And while they are not true generics, you still see conversion at the retail front. It's heartening to see the basic assumptions that we have built into our plan going forward for complex generics, specifically inhalation. These are products that are approvable by the FDA and products that are substitutable. That is the confidence that we get from the recent developments.

As we look at the opportunities in the complex generic front on both inhalation and complex injectables, over the next 4 years we are looking at close to \$30 billion worth of products that will lose exclusivity that we have





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the opportunity to genericize. Of course, we have to execute to really capitalize on this potential.

On the biosimilar front, the market is huge. There has been very limited inroads in biosimilars in the US so far. Nevertheless, there have been positive developments over the last couple of years. As you look at the biosimilar adoption, both approvals as well as market performance, Europe of course adopted it much earlier. You see a number of approvals, over 50 approvals for products in Europe versus 16 in the US. But you see from 2015 onwards, the US FDA has started approving biosimilars. Likewise, when you look at the market conversion to biosimilars, in Europe it has been a pretty healthy ramp up. Europe again adopted biosimilars much sooner and the US is yet to get there. But even as you see some of the products that have had biosimilars participation over the last couple of years in the US, for instance in the case Filgrastim - 70% conversion to biosimilar, in Pegfilgrastim - 33% conversion in the syringes market over the past few months just with two biosimilars. In contrast, it has been less than optimal for Infliximab in the US. There was a real challenge on Infliximab with J&J really putting up a formulary block against Hospira, Greenstone biosimilars. But now we see both Merck as well as Hospira/Pfizer are driving up their scrip conversions on Infliximab.

We have seen, positive developments for biosimilars over the last couple of years that give us the confidence that this market will open sooner rather than later. With all the focus on cost containment on drug spend, the FDA as well as the payers are going to have to drive biosimilars conversion. Over the past couple of days, the FDA also came up with the final guidance around interchangeability. Now there is a lot to be done to really realize the value of what they put in place, but it is a very positive sign. If products are going to be interchangeable, you are able to get substitution and we may not need to really invest big time in commercial resources in driving higher biosimilar utilization which is a material positive.



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Switching to specialty, you know our focus here has been Women's Health in the US and CNS opportunistically in Europe as well as Japan. In the US, we have shared this with you in the past, it's a large market for Women's Health, \$10 plus billion market growing and really there are no material players in Women's Health. All the major companies that were in the Women's Health in the past whether it is Wyeth or Merck or even Bayer, have defocused from Women's Health. Also, the specialty companies that were focused on Women's Health like Teva as well as Allergan have defocused from Women's Health. We see it as a very attractive area for Lupin to build on, Solosec first but also consolidate assets and build a large portfolio into Women's Health.

On the CNS front, the focus is on Neurology in Europe with the Orphan drug that we have launched NaMuscla. In Japan, we have Bipresso for bipolar depression. So, it is really an opportunistic play for us ex-US.

Looking at our strategic growth drivers, just to recap, our three major areas of focus are one - our strong foundation, our base business, primarily our base generic business in the US as well as our India business. Driving growth out of the base business is a big part of our focus. Second has been investment in complex generics, evolving a portfolio and pipeline of complex generics to be able to have a more sustainable and a better margin generic business going forward. And third is specialty, building Women's Health in the US and neurology/CNS in Europe and Japan. Most of our M&A efforts as we mentioned in the past are focused on building specialty primarily in the US.

As we look at our base business today, we are the 8<sup>th</sup> largest generic company by revenue globally, 3<sup>rd</sup> largest from India. In the US we are the 3<sup>rd</sup> largest player by prescription dispensed, we have significant presence in the US prescription market with 6% share. We bring \$15 billion worth of savings every year to the healthcare system in the US. By revenues, we are the 5<sup>th</sup> largest player in India and the 6<sup>th</sup> largest player in Japan. Even in our other markets like South Africa, countries like Philippines and Mexico, we have a significant position. In South Africa, we are the third largest player in the



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generic industry. We have created a dominant position in almost every market where we are present. If you look at our revenues split now, roughly 50% of our revenues are from developed markets (US, Europe, Japan and Australia) and 50% from emerging markets. If you look at our footprint, 18 manufacturing sites, 12 FDA inspected sites that supply to the US. Over \$30 billion of extended unit capacity that the company has created and supplies to the US market in particular. In terms of pipeline, 9 R&D centers spread over India, the US, Japan and Latin America coupled with a significant R&D pipeline. We have a pretty large number of products that are filed with the USFDA i.e. 422. We have 175 products that are on the market, so material pipeline to help us grow the generic business going forward including a pretty rich pipeline of first to files.

As we look at our progress in our second major vertical, complex generics, focus has been on inhalation products, biosimilars and complex injectables. On the inhalation front, in the last couple of years we have made a lot of progress. So now we have Albuterol that is under FDA review. We hope to get it approved by the FDA and launch it in the second half of FY2020. In the last year, we filed our 1<sup>st</sup> DPI - Tiotropium DPI which was confirmed as a first-to-file. This is our largest first-to-file product. We haven't seen anyone else do a clinical study on Tiotropium, so we believe that we will be able to enjoy exclusivity on this product or semi-exclusivity on this product for a period of time. Recently in March we filed the generic to Brovana respule. Multiple other MDIs and a couple of DPIs are in development. So very rich pipeline of inhalation products which we believe is going to be a big part of our generic business growth in the US. We also have an opportunity with the inhalation products in Europe. In select markets in Europe, we are going to leverage our pipeline over the next few years as well.

On the biosimilars front, this has been a material year for us with our successful completion of the global clinical trial on Etanercept, filing Etanercept both in Japan as well as Europe. We got approval in Japan in March. We expect to launch it in both Japan as well as in Europe in second



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half of FY2020. As you know we partnered with Mylan for EU primarily and certain other markets and Nichi-Iko for Japan. We have retained the rights of the product in the US. Beyond Etanercept, we have a few products in development on the biosimilars front. The furthest along is Pegfilgrastim that is completing clinical study this year and will be filed next year in the US.

On the complex injectable front, our focus has been on depot injections out of Netherland; peptides and iron products out of India. We have made material progress on both, the products out of Netherlands as well as India, but the filings will start only in the next fiscal year. We have had multiple injectable approvals this past year. We had four injectable approvals and since then we have got Fosaprepitant approval and we expect to launch injectables into the market in the second half of this fiscal year. So material progress on the complex generic front.

On the specialty front, this is the year that we really started building specialty in full earnest on the Women's health front with Solosec which is a truly differentiated product. We created commercial infrastructure that is dedicated for Women's Health with folks that are experienced in Women's Health, both on the commercial side of the business as well as the medical and the business development front. Solosec ramp up has been slower than we would have liked to see. But nevertheless, we have seen month-on-month growth in Solosec. We have had a challenge with pricing that we shared over the last few quarters and in the last two quarters, we made significant progress both on the managed care front, on the commercial plans as well as on select Medicaid plans to be able to drive access on the Solosec front that we will talk about it in a couple of minutes. We have the foundation in place to build a leading Women's Health business in the US.

In Europe, we launched our first orphan drug NaMuscla®. We had acquired this product through the Temmler acquisition and have developed it. While it is a smaller opportunity in Europe, it is a very profitable opportunity for us. Right in year one of the launch of the product, we have been able to leverage



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the market gap. We launched the product in France through a partnership with a company that was supplying the product. We have launched the product in both UK and Germany with very promising reception. I am very hopeful that this is going to be a material anchor for our European specialty business.

Other than UK, Germany and France, we are in partnering discussions with companies for the rest of Europe. By the second half of this calendar year, we should have NaMuscla® in majority of the European markets. In Japan, we have built on our start with Bipresso. We leveraged our CNS strength in Japan and licensed the first product from Astellas and launched it in 2017. This past year we have grown the product very nicely and enhanced our reach through a partnership with Yoshitomi, to expand the feet on the street to be able to build this product to scale.

We have made material progress on our base business, both in the US generics as well as India and other markets. Made material progress on the complex generic front that will help us drive growth on the generic side of the business in the years to come and progress on the specialty front. We would have loved to make more progress on the specialty front, but we are fully committed to build specialty to a material scale for the company in the US.

With that, I will request Nilesh to come and talk about our business performance for the year.

**Nilesh Gupta:**

Good evening. I would love to just introduce two of our directors sitting here as well. Richard Zahn is an expert on the branded side in the US. He brings in deep insights especially to our specialty play in the US. Dr. Mada is a leading economist and his finance background helps us immensely on the Board. So just like to welcome them here as well.

Moving to business performance, we feel optimistic at this point of time, and if you talked to us a year ago, the story wasn't as happy as it is now. There is



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lot of progress which has been made in the course of the year. I will start with Q4, but I will talk in a little detail about our key markets as well.

As you know, sales for the quarter were at INR 43.3 bn, up 9% year-on-year. North America which is the biggest segment of the pie, was up 16%, India was up 9%. EBITDA at 22.2% of sales. R&D at 9.2% of sales at close to INR 4 bn.

In terms of important developments, on the commercial side - 8 new products were launched. We talked about Ranolazine in the past. Obviously, it was a very important launch in the quarter. We launched Solodyn as well. We had Tamiflu kicking in as the flu season came in, we had pretty much nothing in Q3 and Q4 is when we had meaningful sales, thanks to a late season. The monetization of complex generics has finally started with Levothyroxine launch, that has been a nice launch just right at the very end of the quarter. The story is really to unfold in FY20 and there are other products to follow of course. The India story continues, we continue to outpace the Indian pharmaceutical market.

On the regulatory front, and I will spend some more time on this in a few slides but obviously it has been a mixed bag. On Pithampur Unit 2, the warning letter stays as it is, both Pithampur and Goa were re-inspected. Pithampur had 6 observations, Goa had 2. Pithampur status remains as OAI. At Mandideep, we had 18 observations, which was also classified as OAI and Somerset, where we had 6 observations was classified as OAI as well.

In terms of the pipeline, it has been a great year. We talked a little bit about Etanercept but getting that approval in Japan, for a product that was developed in India, with facilities only in India, a trial which span multiple continents including India and getting an approval, that is no mean task and it really paves the way for future products as well. There were 12 filings in the quarter and received approval for 7 ANDAs.



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For the year itself, overall sales were up 5%. North America declined 5% on a Y-o-Y basis. India was up 12.4%, APAC was up 2%. EBITDA came in at 19.8% of sales and R&D was at 9.6% of sales for the year at INR 15.7 bn. Obviously the complex generics pipeline is starting to kick in. We have launched Solosec. It is still early days. I will spend some more time on Solosec in a little bit, but clearly, we have a lot of aspiration on that product. In India, we expanded our partnership with BI and Lilly adding 3 more products into the Anti Diabetic portfolio. We possibly have the best Anti Diabetes portfolio in the country. We partnered for Etanercept with Mylan and Nichi-Iko, as Vinita mentioned. And lastly the MALT1 licensing, it was DBG's dream and vision to do drug discovery. We were very happy to take it forward and to finally culminate it into this licensing, for a preclinical that is one of the highest that anybody has received as an upfront amount. The total milestones are very significant as well and you always tend to discount these as R&D dollars, but we feel very strongly about this program and there are several other programs which are in advanced stages as well. On the pipeline, solid year - 28 filings, 11 first-to-files, 30 ANDA approvals in the year, 2 inhalation filings including Spiriva as Vinita mentioned and Etanercept as well. NaMuscla<sup>®</sup> was also approved in Europe with an orphan drug indication and we launched it in UK, Germany and France.

Switching to North America, which is 34% of our sales, posted solid performance during the quarter, with year-on-year increase of 16%, and sequential quarter increase of 23%. Rising quarterly sales curve in US with US\$168mn to US\$171mn to US\$194mn to US\$245mn from Q1 to Q4, clearly shows the business shoring up in the US. Another statistic, which I am proud of, is our average market share, which is the highest amongst our peers. 33% is the average market share per product that we enjoy, and really Alok's task is to take every new product to that 33%. So that is something that we feel really good about. And if you really see over the years, we now have 65 products where we are market leaders, 129 products where we are in the top 3. We see that statistic improving year-on-year. Solosec, as Vinita mentioned,



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it has been almost a year, but it is still early days for the product. Very solid ramp up just between Feb and March. We have jumped to 7,000 monthly scrips, still a long way to go. The momentum really sets us up for FY20 where we expect this growth to continue. The managed care coverage is well characterized at this point of time and now we can really target well to get the right sales out of this product.

Some of the big wins was getting Medi-Cal, that is the Medicaid program for California. One of the toughest programs to get into actually and it will be a real nice uptick in business on that count. We just got that in May, along with others Blue Cross Blue Shield. There are a lot of formulary wins that are happening. None of us are satisfied with where it is at this point of time. The sales curve needs to continue its uptrend into all of next year as well and that will take us to a pretty good place for Solosec.

In India, again like Vinita talked - consistently outperforming the market, 29% of our sales for the quarter, year-on-year increase of 9%. Q4 is usually the weakest for the Indian pharmaceutical market and the same holds true for us as well. But if you look at the sales, pretty good solid sales through the quarters on Y-o-Y basis. Our sales increased 12.4% Y-o-Y, while the market grew 10.5% in that period. This has obviously led to a lot of good things, two brands in the top 100, 8 brands in the top 300, 5<sup>th</sup> rank overall. There are months where we are now starting to get to the 4<sup>th</sup> rank in India and that is the path - three years ago we were number 9 and have been improving our ranking consistently. The Goal is clearly to be in the top 3. 60% of the contribution comes from the chronic diseases. The India market continued its outperformance. The PCPM is INR 7 lakhs, it is one of the best in the industry and it has really improved over the years. It was INR 5.6 lakhs going to INR 6.3 lakhs and now over INR 7 lakhs per month and this is on the back of adding new representatives as well. We have a rich in-licensed portfolio of 34 brands and close to 7,000 representatives now. We added some 350 representatives in the first calendar quarter, and we spun out some 2 or 3 divisions out of that as well.





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On Japan - which is 13% of our sales, grew 8.6% year-on-year for the quarter. In the Japan market, generics are growing, but they are growing in volume, not in value with the annual price cuts. There is a lot of pricing pressure. But I think- patent expiries and the fact that this is now in many ways a substitution kind of market, starts driving the game more towards driving R&D efficiencies, manufacturing efficiencies and getting meaningful market share. We were pretty even through the quarters on the sales front. Biosimilar Etanercept was approved, and we will launch that in the second half through our partner. Bipresso Q4 sales were up 125% QoQ. It is still extremely small and that is one of the reasons why we have partnered with Yoshitomi. The average physician market share coverage that we had was about 55%, with the Yoshitomi relationship its now 90%.

Now I am going to touch on all the other markets. In particular Germany did well, EUR7 mn sales in Q4. The ARV portfolio is coming around well, especially in markets like Europe. Australia continues to do well with we being the 5<sup>th</sup> largest generic player. Revenues were up 7.4% year-on-year. South Africa continued its extremely solid performance, being the 4<sup>th</sup> largest generic player, and the largest CVS player, revenues were up nicely as well. LATAM had pressures, especially markets like Brazil where the transporters strike hit us badly in the course of the year. Grin continues to be the #4 ophthalmic player. The API business obviously had a very solid year. It grew 23% on a Y-o-Y basis for the full year. And then the TB institutional business presence continues where we have a dominant share.

We have really optimized the R&D spend now. You now see that flat ~9% of sales on a regular basis. The filings and approvals continue. It has been a pretty solid year. 422 filings to date, 157 pending approvals, 40 first-to-files (15 exclusive first-to-files out of that and 11 first-to-files were filed in FY19). Even on statistics like first cycle approvals, we are well above FDA's average. It has always been a good hygiene coming in, not just on optimizing the spend but making sure that products get delivered in the right timeframe as well.



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Now I am moving on to the EBITDA evolution through the quarters. You can see that progress quarter-on-quarter, 19% going to 20%, going to 18%, going to 22% and then that absolute increase in EBITDA as well. As the sales have increased, we have been able to take a lot more to the gross margin then to EBITDA line. So very solid operational performance at this point.

On cost optimization, we have talked about this a little bit in the past but there is a very clear goal especially for FY20 and FY21 that we need to drive a lot of cost efficiencies. In the longer timeframe the bigger growth drivers need to kick in, complex generics, specialty, biosimilars. But in the near term, there are really 3 areas that we are focusing on from a cost optimization perspective. On the strategic front, very sharp focus on US and India more than any other market and we make sure that we deliver in both of those markets. Improve R&D productivity, we have optimized the R&D team size a little bit, but we also have to focus on productivity, getting products filed in the most expeditious manner, getting products approved and launched as early as possible as well. Building that agility in supply chain - as competitors have gotten out of the market, those have been nice opportunities for us. We think we can do a lot more on that front as we optimize. So that is another focus area.

On the organization, clearly the goal has been what is the model going forward and what size and what shape does the organization have for that. It is really aligning the organization structure to the future strategic direction. So that was another big initiative we took on last year. And then on the operational front, we always did this but there has been renewed focus across the company. There are no holy cows anywhere when we have been looking at this in terms of procurement efficiencies, improving throughput, optimizing that cost base and creating that center of excellence for support services. There is a decent bit of it that will come out in FY20. But there is a much meaningful piece which will come out in FY21.



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On the regulatory update, we have two sites under the warning letter, Goa and Pithampur Unit 2. It has been a mixed bag for the year. There have probably been a dozen inspections, there have been 3 or 4 which have not gone as well as we would have liked them to. Unfortunately, those are the ones that only get talked about. But there has been a whole bunch of successful ones as well. A lot of EIRs, but focusing on the key ones, we got EIRs for Pithampur Unit 1, Unit 3, Nagpur was inspected a couple of times, that is our new finished product site, both times with zero 483s. We have received those EIRs as well. We received EIRs for our API facilities like Tarapur that were inspected. On the flip side, Mandideep which was inspected in December, the performance was far from satisfactory. We had 18 '483s that was subsequently classified as an OAI. In January, we had inspections for both our Pithampur Unit 2 and our Goa sites; 6 '483s in Pithampur Unit 2, 2 in Goa. We haven't heard for Goa at this point of time, but for Pithampur the status was retained as an OAI status. Somerset also had 6 '483s post inspection and that was classified as OAI as well. Again, we are far from happy for where we are on the regulatory front. There is a lot of work that we need to do. There is a good amount of clarity on what we need to do as well. FY20 has to be the year where we have to work on these warning letters and these OAIs and turnaround at least a couple if not all of them. We have given very solid responses to, for example, the Unit 1 OAI or to the Somerset one as well as part of our regulatory updates. Let us see how it goes in the next couple of months.

In terms of priorities for FY20, first step - protect that strong generic foundation. Focus on the regulatory compliance, warning letter resolution, OAI resolution as well, ramp up Levothyroxine, we are already chasing that plan for capacity. We are already doing an expansion to be able to take care of volumes that we feel will come. 20 plus launches planned in light of the warning letters and the OAIs. As we get clarity for Goa or Unit 2 or Somerset, we will have an even bigger portfolio of products to launch. Continue growth in markets like India and some of the emerging markets. On the complex



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generics front, gain approval of Etanercept in Europe, launch in both Japan and Europe in the second half, file some more additional inhalation products. There are a couple of MDIs, DPI in development as well. For injectable products, there are several filings planned. Finally, launch gProAir in the second half.

On the specialty front, clearly Solosec - we need to scale up Solosec significantly. We want to see that performance really improve quarter-on-quarter. We have a good 9 plus years of exclusivity on that product. There is time, but we have to get it right. The intent is to get it right in the near term, not have it drawn out. Again, the idea is not just limited to Solosec, we are really building that scale in Women's Health through internal development and through alliances from the outside as well. Also build up NaMuscla® in Europe and ramp up Bipresso in Japan. On the cost optimization, again focus on the productivity, deliver on the measures that I just talked about and really sharp focus on resource allocation.

The last year has been a very exciting year. There had been highs and lows, but it has been a pretty exciting year from a business perspective. FY20 offers even more opportunities. It has its share of challenges as well, but there is a lot of stuff to do. A lot of stuff that got done in FY19, but a lot more stuff that we will do in FY20. Thank you.

**Vinita Gupta:** We will be happy to take questions.

**Participant:** Thank you sir. Just want to understand, what kind of cost savings we can see in FY20 and 21 and it will be coming out of which heads?

**Nilesh Gupta:** Again, we have not shared this with the outside of course. I don't think we want to do it because it sets the wrong expectation from an internal perspective to be honest. But we are looking at everything. So just some of the key areas will be manpower optimization. We have actually taken significant cuts in R&D, in salesforce in the US and Japan. There are still other



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areas that we are looking at as well. There is a very aggressive drive on alternate vendor development, in APIs, excipients, packaging material as well. Some of it we used to do, but a lot more aggression than ever before. Part of it has just been focusing on certain areas, not diluting focus in some of the other markets. Focusing on markets like US and India, and not diluting by additional R&D spend on some of the other markets. It is a good number, just don't want to share as it will set the wrong tempo within Lupin, and once we deliver it and there is a budget for FY20 as well, we would be very happy to come back and talk about it after.

**Participant:** And just a follow-up. The other question on the injectable side you said that there are couple of launches in the second half. Can you give more light on that?

**Vinita Gupta:** Yes, Fosaprepitant is one of them and then Azacitidine is another and couple of others that we are looking at right now. We have the potential of bringing in our own products as well as partnering with companies to bring their portfolio to market.

**Participant:** And coming to the facilities which are running with issues, so will there be any impact on the launches?

**Nilesh Gupta:** The launches that we have guided towards are in light with the fact that there is an OAI status on all of these as well. Today we had the Aurangabad inspection, we had 3 '483 observations. We believe that it is very simple to respond to these observations and then close that as well. All the other sites are inspected, and they all were inspected in the last year. What I said was we have not taken an upside from any of the facilities that have an OAI or the warning letter. As we clear them, those will be additional products. But the 20 plus product launches happens any which way.

**Participant:** Question on the R&D side, we have seen lot of optimization, rationalization on the R&D side. How do we look at it next year? I mean, some outlook on



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that given the fact that you spoke about from the injectable side, you want to develop or you already developing depot and then the inhalation more products coming in and thirdly Enbrel in the US. So what is the plan there?

**Nilesh Gupta:**

We resized our R&D about 2 years ago. What we are seeing is how these aspirations have changed over time, some of it we actioned last year, but the product portfolio was repurposed in the course of the last 12-18 months. Oral solid opportunities obviously going down over time. The interest very clearly is to move into injectables and to more of the complex generics. What we have done is we have taken away from some of the oral solids without leaving opportunities on the table. The intent was we know that area best, so we are not going to leave anything meaningful which is halfway in the development as far as oral solids are concerned. Some of it obviously got repurposed to injectables, especially in the course of this year you will see an increase in R&D spend on that. We already had a pretty healthy number when it came to areas like inhalation or complex injectables and we have also had funding options in those areas. There has always been an ability to do the products that we wanted. When we resized the R&D, the intent very clear was to not give up opportunities, but it was to focus on the right one. There is a more finite list at this point of time. But I don't think we are giving up opportunities, not for the next two years, but not even for the long term. The intent is very clear to keep delivering. Even on biosimilars, we had a pretty healthy budget when it came to develop Etanercept and that is the kind of budget that will continue to support other products as well and again there is pretty good commercial interest as we saw in Etanercept, there is pretty solid commercial interest to partner to bring these products in market anyway.

**Participant:**

So Depot and Enbrel in US will start in 2020 itself, is what I was trying to understand?

**Nilesh Gupta:**

The Depot injections are already under development. So those have been going on for the last couple of years. In terms of the complex generics that is possibly the toughest area that there is. And we have been close, but we have



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had setbacks couple of times as well. Again, we have human development studies going on at this point of time for the Depot injections for the US. And clearly those will go to some of the other markets as well. On Etanercept, the intent is really to do a bridging study and to do some of the US specific studies that are underway.

**Vinita Gupta:** There is a patent as well that has been challenged. We will look at the outcome of that patent challenge as well. If we have the opportunity of launching earlier, we will launch earlier.

**Participant:** Thanks. And R&D should be around 10%, right, of your sales?

**Nilesh Gupta:** Yes.

**Participant:** Can you share some more color on NCE?

**Nilesh Gupta:** Sure. We have done NCE work for more than 10 plus years and clearly the model was always to do a Phase-II and license out. The idea was never really conversion to specialty or our branded efforts. But over the course of the past few years, we had a few assets that had progressed nicely. We have two other assets that are in clinic. We are waiting for clinical data for both in this quarter and intent would be to partner them on the basis of that successful data. The MALT1 program was a pre-clinical program. It was set to follow to clinics after these ones. We will have two other candidates where if the clinical data works out favorably, these will also be good candidates for licensing as well. In the longer term, where NCE fits into the bigger scheme of things - one part of it is obviously what we can repurpose with specialty, particularly to Women's Health for example and if there is something that we could do. We are also looking at some of these late stage assets that we have, if there is a way to commercialize them ourselves, is that an opportunity as well. There are a few thoughts going on in that. We are trying to bridge that gap and get convergence with the rest of Lupin's business strategy. But right now, the model seems to be licensing out.



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**Participant:** So you have a significant amount of goodwill in the books. Could you maybe consider writing it off more aggressively to right size the balance sheet?

**Rajiv Pillai:** So that is as part of the accounting standards and the audits that take place on regular basis, periodic, quarterly as well as annual. There is impairment testing that takes place. There is a very robust process. We are evaluating those. You saw some of that write down come in last year. There are lot of guardrails around that and we are confident about the goodwill we are holding in our books as of now. And this has been tested on a regular basis.

**Participant:** I have a couple of question. Just a clarity, you said 20 plus products in US launches or you are taking about approvals?

**Nilesh Gupta:** 20 plus launches in the US.

**Participant:** And how much product we have approved but not launched yet?

**Nilesh Gupta:** A good number of them are not approved at this point of time. But we don't see any reason why hiccups would come in the approval of those products

**Participant:** Fine. And related to this Q4 numbers, just tax rate was on a higher side. So that particular reason?

**Rajiv Pillai:** The tax rate that you saw was abnormally high. That is more of an optical thing, because we have significant profits residing in India and on which we are paying a higher rate and we have losses in other entities which reduce the denominator. Case in point is that Perindopril litigation provision where we don't get a tax break on that but reduces our profit and therefore, it kind of inflates the ETR percentage. That said, yes, this year a lot of profit was residing in India. The losses in subsidiaries outside are primarily on account of investments that are taking place and over the next few years they will equalize and will come back to more normalized rates.





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**Participant:** So what should have in normalized rate if that optical things are removed then?

**Rajiv Pillai:** If those losses are not there, then it should be around 30% but I want to caveat it by saying that since we are making those investments today, progressively you will see that downward trend. It is not going to happen overnight or a single quarter or a half year. But it will happen progressively over the next couple of years or more.

**Nilesh Gupta:** Pointedly for FY20 we think it is going to be more like 40%. But long term we believe that we will bring it back to that 30% kind of number that we had for the longest time.

**Participant:** And last one, from industry perspective from Sharma Sir, what I see our Jan Aushadhi is now panning out all over India and lot of things are going on, on a paper. What actually is happening on ground, we wanted to understand? Secondly, we see a lot of reason and a lot of initiative towards healthcare segment as a whole. But for pharma, we do not see any long-term vision from government side or if you could throw some light what government has a vision to save this pharmaceutical industry excluding this healthcare part of this industry?

**Dr. Kamal Sharma:** You know, ever since we have been reading about healthcare efforts on the government, the three elements that they keep addressing are the affordability, accessibility and availability. Unfortunately, there is a lot more emphasis on affordability and that is why you hear of Jan Aushadhi and state governments buying medicine under tender. There was also a move couple of years back to seek generic prescriptions even for complex products which in fact has been now put on back burner for some time. But in India what is even more important, is the accessibility of healthcare. If you look at any micro parameters in terms of beds available per 1000 or doctors available per 1000, it is really towards the low end. If you take beds like 3.3 per 1000 in India, you would have some 1.1 or 1.2. A lot more needs to be done in terms



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of infrastructure. Lot more needs to be done in terms of insurance because most of the payment is out of pocket in India. But unfortunately, we hear all the stories about affordability. The pharmaceutical companies which constitute only 15% of healthcare business, remain always under pressure. I reckon it is going to be a subject matter of politico economic situation in every administration. We see it around the world, and we have to remain alert to some of these provisions and make sure that the business responds effectively to whatever regulations, situations come our way. That is my view.

**Participant:** Good evening. Quick question on Spiriva. What is the way forward for it, especially given the multitude of patents? What is the best case of when would you be taking it to the market?

**Sofia Mumtaz:** That is a difficult one. We do have a very strong position but as you know it is a litigation, the best-case scenario would a launch sometime in 2022.

**Participant:** Is device patent blocking you?

**Sofia Mumtaz:** The device patent is listed in the orange book, but we have a very good position on that.

**Participant:** And in terms of its ANDA approvals, any thoughts on this as the first DPI coming from the stable?

**Vinita Gupta:** Yes, that is right. We think that we have a very solid application with the agency and we of course have until the 2022 date. We have a bit of time. We think there will be a back and forth with the agency. But given the Advair success that Mylan has had, that gives us the confidence that we should prevail on Spiriva. On the facility front we already got the EIR on Unit 3 from the FDA. So that is clear.

**Participant:** Okay. And just on ProAir. Are there any pending questions from the FDA?



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**Vinita Gupta:** No. We have submitted responses to all their questions. We hope that is going to be a second half launch in the fiscal year and we hope that the FDA does approve it. Now the FDA has not approved any MDI so far. So there maybe hiccups with the complex generics along the way but we are committed to getting that product through.

**Participant:** Do you have any date given by FDA on this?

**Vinita Gupta:** Yes, we have a date. But we have a launch date which is more important given our settlement.

**Participant:** And you think you will be on time for that?

**Vinita Gupta:** We hope so.

**Participant:** Okay, great. One on Etanercept, for Europe what is the timeline for CHMP?

**Nilesh Gupta:** It is in the second half of the year, October-November is the timeframe that we are looking to get an approval and launch possibly likely in the last quarter.

**Participant:** One final question from my side. May not be a very comfortable one, but the current lawsuit which has been filed on drug price fixing in the US, your top level thoughts what's going on over there?

**Vinita Gupta:** We think that is too much of a focus on drug pricing. And we believe that these are mere allegations and we of course will defend up the company vigorously. We operate with a very high level of ethics from our business standard standpoint not only in sales and marketing but the rest of the organization as well and believe that we will be in a very strong position.

**Participant:** This question is for Nilesh. Nilesh, last year same time we were reasonably excited about Solosec. So that was supposed to be a big catalyst this year. While you did concede to the challenges that are there in the ramp up, you feel reasonably optimistic as reflected in the number that you share with us.



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Could you just share what are the challenges to reaching this number and what is the source of the optimism around it?

**Nilesh Gupta:**

I am going to do full upward delegation at this point of time.

**Vinita Gupta:**

So, the first year certainly was challenging for us. When we look at the scrip ramp up, it was not at the level at which we had hoped. Big part of the challenge was the pricing of the drug and while we had good coverage for the product right from launch, we didn't necessarily have an optimal match of the rep in the Doctor's office aligned with the coverage in a particular region. So midway through the year in October, we offset some of that price burden through our coupon program and we immediately saw a jump in our level of scrips which confirmed to us that pricing is a challenge on the drug. As we look at analyzing the past, look at the last 12 months and what has happened with Solosec, what gives us confidence and optimism? One - top decile writers, a good number of them have written Solosec. If I must look at some of the highest volume writers, they were willing to convert 20-25% of their prescription base to Solosec. So, what do we need to do to really get that kind of market share across the larger market? We need to replicate that success with a larger percentage of the HCPs, a larger percentage of the nurse practitioners. The second area of focus, are the folks that adopt, wait and see, have seen that the drug is safe and effective for physicians that have used it, have found that it is very effective, and we will see utilization go up. We are seeing that on a consistent basis. On the pricing front, we now have better formulary coverage both on the commercial plans as well as Nilesh mentioned select Medicaid program. On the commercial plants, we have now got access to some more - the Blue Cross Blue Shield in Tennessee, Harvard Pilgrim in Florida. Medi-Cal is a huge pick up for us, particularly in California. We are now directing a lot of the rep effort into California to be able to really pull that through and we are certain that we are going to see a spillover effect also on to the commercial side of the business. On the access front we have been able to offset price. We have been able to get better formulary coverage and we have been able to get into strategic Medicaid plans that help us drive



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utilization, create more access for the product. We have not seen any material complaints for the product. There have not been material adverse events. There have been issues with the taste when people really grind on the product, which they are not supposed to do. The product is safe, effective, physicians that use it like it, access which is a problem, we have been working on it and will continue to work on it. That is what gives us an optimism to drive growth.

**Participant:** Thanks. That is helpful. My second question is, your thoughts around the fact that while these two at this point of time stages allegations, but the recent developments, do you think they kind of prevent you guys from taking price hikes as a consequence of withdrawal of certain players, generic industry as a whole will be much more cautious in taking advantage of opportunities which are market situations where players are exiting throws up?

**Vinita Gupta:** I will let Alok answer that question. Price hikes are not illegal.

**Alok Sonig:** Price hikes are not illegal. We will price based on what obviously the market can bear and where we can go in and create value. As we mentioned, we are obviously first and foremost at 6% share and save about \$15 billion for the US healthcare system. We will obviously take suitable action to optimize the value, where we can leverage the market situation based on market customer competitive insight. So, it is not out of bounds.

**Nilesh Gupta:** Thank you.

**Moderator:** Thank you very much. On behalf of Lupin Limited that concludes the conference. Thank you for joining us ladies and gentlemen. You may disconnect your lines.