



June 1, 2016

✓ **BSE Limited**

Department of Corporate Services,  
P. J. Towers,  
Dalal Street,  
**MUMBAI - 400 001.**

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
**Mumbai - 400 051.**

*Dear Sirs,*

**Sub: Annual Investors Meet.**

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 meeting of Investors and Research Analysts held on Thursday, May 19, 2016 at Mumbai.

Kindly confirm having received and noted the above.

Thanking you,

Yours faithfully,

**FOR LUPIN LIMITED**

**R. V. SATAM**  
**COMPANY SECRETARY**

Encl.: a/a

LUPIN LIMITED

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Corporate Identity Number: L24100MH1983PLC029442 [www.lupin.com](http://www.lupin.com)



## “Lupin Limited Q4 & Full Year 2016 Earnings Conference Call”

**May 19, 2016**

**MANAGEMENT: DR. KAMAL K. SHARMA – VICE CHAIRMAN, LUPIN LIMITED**  
**MS. VINITA GUPTA – GROUP PRESIDENT & CHIEF EXECUTIVE OFFICER, LUPIN LIMITED**  
**MR. NILESH GUPTA – GROUP PRESIDENT & MANAGING DIRECTOR, LUPIN LIMITED**  
**MR. RAMESH SWAMINATHAN – CHIEF FINANCIAL OFFICER, LUPIN LIMITED**  
**MR. ALPESH DALAL – HEAD, M&A & IR LUPIN LIMITED**  
**MR. SHAKTI CHAKRABORTY – IN-CHARGE HEAD, INDIA BUSINESS, LUPIN LIMITED**  
**MR. RAJEEV SIBAL – PRESIDENT, INDIA REGION FORMULATIONS. LUPIN LIMITED**  
**MS. SOFIA MUMTAZ – PRESIDENT, IPMG, LUPIN LIMITED**  
**DR. RAJENDER KAMBOJ – PRESIDENT, NOVEL DRUG DISCOVERY & DEVELOPMENT, NEW CHEMICAL ENTITY RESEARCH (NCER), LUPIN LIMITED**  
**MR. PAUL MCGARTY – PRESIDENT, LUPIN PHARMACEUTICALS INC.**



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**Ramesh Swaminathan:** A very warm welcome to everybody out here; very happy to have you back, especially when the results are so good. I'm sure you've already gone through the results and a lot of you've already spoken to me and asked me a lot of questions. Indeed, when we began the year, we said the first two quarters are going to be little lackluster, but we did promise that the third quarter and fourth quarters, you'll see a remarkable turnaround and more than that, actually. And we lived up to our own expectations. This fourth quarter, we closed our accounts with a record turnover, over INR 4,000 crores, for this particular quarter.

I've been advised that there are people from abroad joining in, and we have a call. So let's wait for a few more minutes.

There are several qualitative aspects to our turnover for the quarter, of course, there is a 9% growth for the full year, when we speak about the performance vis-à-vis the previous quarter that is 22% up, 34% up vis-à-vis the last year itself. While these are a good set of numbers, we are happier with the gross margins performance also; 74% for this particular quarter and if you look at the performance for the year, it is 68.7% while it's even higher than in the last year. It goes to show the quality of the products we launched in the market fourth quarter. Of course, it follows through with the EBITDA margins – which for this quarter was 34% whilst for the full year it is still a tad lower than the last year, but I would attribute that a very high R&D expenditure over Rs.500 crores, which would have translated another 3 percentage points. If we add both, we come to EBITDA margins even higher than last year. Of course, the PBT, again, despite the fact that the R&D expenditure was high – was higher than last year and if not for that for the higher quantum of tax, the PAT itself would have been considerably high.

And on that last note, may I request Dr. KKS to make the presentation?

**Dr. Kamal K Sharma:** Good Evening, Ladies and Gentlemen. Thank you, Ramesh for those opening remarks. You've already seen the results, and Ramesh gave you a snapshot of where the financials have worked out. I think, I'm going to walk you through some of the industry trends as they are mopping, and how does Lupin that come in the face of those trends, and finally look at the quick dive into the financials, and end by saying as to what we are going to be doing, in the coming years.

So, when we speak about the trends, something which has been very prominent in the recent past, is the erosion in prices in the US. And as you are aware that there has been substantial consolidation of the channel partners, and therefore it has obviously helped them to improve their bargaining power and the differential price in that one could earlier enjoy that is no more there. So, there is a block price for a group of channel partners, and I think the last one which happened was recently was



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McKesson and Walmart, right. So, that really has been -- you know, generally, the US market -- Generic market will experience about 4% to 5% price reduction, of which at least 50% one would be able to make up through operational efficiencies but this particular episode has led to double-digit reduction to the tune of 14-15%. Of course, what is positive, is a better score on approvals by FDA. There has been substantial improvement in that area which had hitherto been deficient.

When it comes to India, we are all aware that NLEM has set a new order as far as the Indian business is concerned. And whatever was the impact of the first NLEM policy, there has been further reinforced with what has happened in 2015 and the latest one that we have been dealing with is the ban on fixed dosage combinations, there is a temporary respite for part of them because we have a stay order but how it's going to pan out is anybody's guess. In sum and substance, there is a pressure on the business in terms of control on prices and ability to launch new products.

Japan – the government has been progressively working towards improving the penetration of Generics, it is targeting 70% by 2017 and 80% by 2020. But on the other side, Japanese administration is also pushing prices down, I think, earlier we used to experience reduction in price every two years, now it's become an annual feature which is not a very good news.

There has been substantial consolidation in the industry in the last 2.5-years; M&A of \$500 billion has happened and most of you have been reading in the papers of the major mergers which have taken place in the recent past.

Another development which is worth citing here is that Biosimilars which is kind of a new wave in Generic market. They are now seeing a lot of traction on the guidelines, pathways from the regulators in Europe and in America and hopefully in the next few years there would be a lot more clarity in taking these to the markets. There are already instances where US is approving Biosimilars for the market.

The year witnessed a lot of penalties from USFDA on the manufacturing plants. And while we have had a stellar record, we did not escape the heat and we will talk about that.

Coming specifically to United States. What is in store for us in terms of trends, is that the Generic penetration is expected to rise from the current 88% to 92%. Between now and 2020 there is likelihood of \$92 billion worth of patent expiration, which is an opportunity in Generics. This obviously augurs very well for the business. We also understand that the lion share of Generic goes to oral solid dosage forms, and a lot more needs to be done in the alternative forms. And the generic industry despite all the consolidation that we keep hearing about and we keep witnessing remains very



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fragmented and in that sense if you see the top five operators in generics in the United States have lost their contribution from 55% to 51%, market share has come down.

This is what I will say, meaning, when I said that the dominant share is with the Oral Solid Dosage form, in the slide that we see on the screen, you would see that there are 47 players in the OSD whereas as you go to the right of the slide you would see that there are a lesser number of players and there is a lot of concentration in the hands of few. The idea of sharing this information with you is to say that there is a lot of scope to grow in alternative dosage forms other than OSD and that's what, is the world of Complex Generics and specialty which we're pursuing in the company.

What does this trending mean for Lupin in particular? I think we've already started our journey towards Complex Generics, we need to focus on it a lot more, we need to build Specialty both internally as well as through acquisition and partnerships. In India, I think the way the trends are, if we are going to be controlled on new launches, if there's going to be price pressure, I think, the alternative is to increase your prescriber base and as we have demonstrated in the past we need to create more alliances: a) we need to go deeper into the existing alliances, as I speak with you we have four alliances in India with multinationals, and whatever we are doing with them, we need to go deeper, in addition, b) we need to tie up with more partners, so that the growth is ensured.

Likewise in Japan, I think if one wants to deal with the price pressure, the only way it can be done is to launch more products and -- in order to do that I think we need to seek more strategic partnerships and of course we are already undertaking capacity expansion in Japan to be able to serve the market better.

As far as M&A is concerned, I think we have stated in the past and our policy remains as we have said in earlier that Lupin would look at select areas of brand and specialty and niche technology platforms when it comes to merger and acquisitions.

We've also stated earlier about our geographic expansion endeavor and I must say that in future you might witness some bolt-on acquisition, but by and large, as far as the geographic expansion is concerned for the company, we seem to be there, I think what we need to do is really now make these new acquisitions grow and consolidate them rather than expand geographically any further.

Derived from the focus on Complex Generics and Specialty, I think it is a natural corollary that the R&D investments have to get enhanced in Complex Generics and the Specialty area and also in Biologics and you already see that escalation happening as we will discuss the financials.



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As far as the execution is concerned, I think we've always revered for flawless execution and operational excellence is one of the key drivers of our effort there. We want to make sure that we are cost leaders in whatever we do.

And that brings me to sharing with you, what we have been sharing in the past too as to how we see Lupin mopping, from a Generic – Branded Generic Company till now into Complex Generics, Specialty Company going forward and the share of Complex Generics and Specialty has to increase with the Generic component of the business. Generic would always remain a very lion piece of the business, as you know that, at any given time, very large part of illness is served by patent expired drugs. So one cannot do with that but larger attention would be received by Specialty and Complex Generics in our business.

So that's about the trends that we are kind of witnessing in the industry. In the face of those trends, I think its worthwhile looking at how Lupin stacks up to this challenge. I think one feels very proud to share journey of last 10-years with the audience here. It has been a stellar performance by any standards. If you look at the market capitalization, I think, there's a compounded annual growth rate of 32% from kind of Rs.41 billion to Rs.667 billion. Revenues have registered a growth of 24% in the same period. R&D expenditure has also gone up with 31% growth and this is something which -- you know, R&D is a key driver of our business endeavor in Pharmaceuticals and therefore requisitely we've been investing in the priority areas in R&D. What is most heartening is the quality of our business where you see our EBITDA margins growing at annual compounded rate of growth 29%. There were times when we were struggling around the 10% and you know 18-19% for a long time. We've crossed that barrier and we are now around 30%. Likewise, net profit also has shown very promising growth of 29%. So that speaks about the way we have organizationally strengthened our company.

As a consequence of that, we are today 7<sup>th</sup> Largest Generic Company Globally by Market Cap, 9<sup>th</sup> Largest Company by Revenues, we are the Third Largest Indian Pharma Company by Global Sales, #1 Anti-TB Company which is our Legacy business, we are the 5<sup>th</sup> Largest Company in the United States by Prescriptions; we have a prescription share of 5.6-5.7%, we are the 9<sup>th</sup> Largest Generic Company in Japan, 8<sup>th</sup> Largest Indian Pharma Company and the 4<sup>th</sup> Largest Generic Company in South Africa and #1 Cardiovascular Company in South Africa.

With the good work that the team has done, it has brought along the accolades that the team deserves. The notable ones, that I may mention here in the long list that is in front of you, is being designated as Outstanding Company of the Year by CNBC-TV18, Lupin was ranked as "15<sup>th</sup> Best Place to Work for in Asia" by Great Places to Work Institute, we have been ranked as one of the best employer of 2016 in India by



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AON. Vinita Gupta and Nilesh were awarded the Entrepreneur of the year award by Ernst & Young. Vinita has been in the focus for various awards, as you can see the list there and I think the notable one has been the Power 50 Women in Business and last but not the least is Ramesh Swaminathan who has been recognized as The Best CFO by FinanceAsia.

When we speak about Lupin today and how it stacks up against the trends and the challenges that I shared in the beginning of the presentation, I think what we are doing with our head down as a team in the company, is to build a global footprint for the company, both through the internal development of capabilities as well as acquiring capabilities from the outside through M&A, wherever we feel either the lead times are going to be very long or we just don't have the wherewithal from within to build those capabilities. And in that regard, you would see here, that we have set up a state-of-the-art R&D facility in Florida for Inhalation, we have our first Biosimilar order for Pune facility getting into Phase-III Etanercept, we had a stellar launch of Glumetza and a lot of positive movement that we are seeing today is because of that and we hope to continue to do launches like that in future too.

On the Inorganic side, we used to hold 60% equity in the South African company, is now 100% ours, so we acquired the 40% remaining equity from the erstwhile promoter, we have acquired a business in Brazil Medquimica, we have acquired Gavis which is our largest acquisition and one of the largest out of India, we also acquired a small CNS portfolio in Germany called Temmler.

We've always said that you know our inorganic play would be not to chase size but to chase quality. And I think that's what the slide here would show you that of the entire growth story that Lupin has experienced, 20% of our revenue comes out of inorganic endeavors or inorganic interventions and 80% of that is really our organic effort. So that speaks for the team, as to how well integrated they have been, in terms of achieving the kind of target that we had set for ourselves, which have always been very stretched. And I think another highlight of the journey is that whatever we acquire along the way that too has grown extremely well. So if you see Kyowa that we acquired in October 2007 has registered a compounded annual growth rate of 16% on constant foreign exchange. Likewise the South African asset Pharma Dynamics has grown 25% in the period. So, that shows that whatever we acquired has also been producing results and growing at a very healthy clip.

Gavis which is now called Lupin Somerset is our biggest and by far the latest acquisition. And while we were kind of endeavoring to have it by mid of last year, but we could close it only towards the early part of this year, but what is important is that performance is on track, the integration is complete, we have a new leader there, who is an extremely competent person and we hope that whatever we have planned,



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in terms of tripling the turnover of Lupin Somerset from the time of acquisition, we will definitely be hitting the bull's eye there.

What is even more interesting to share with you that in the portfolio of Gavis, we could get to reach for our Branded business. You know that we are very proud of our Branded business, but for various reasons it had been going down because we lost intellectual property rights on a particular product, it became Generic on Suprax, but these two new leads – one on Methergine which is for Women's Health and other one, you know, methylphenidate chewable tablets for the Pediatric ADHD indication is giving a new lead to our Branded business and also gives us little more time to really push hard in terms of other efforts that we have been making in building that business.

I think you are all aware that in terms of net effect of Gavis on Lupin's portfolio it has added 28 products to our marketed products, so total 124 products are there in the market today. There are 9 controlled substances and 01 dermatology product out of this basket. There are about 102 cumulative filings, of which 58 are pending and additional 66 products are under development.

Lupin has a good score in terms of our total filings; now we have filed, between Lupin and Lupin-Somerset that is our new facility, Gavis, 343 filings, of which 180 have been approved and balance are awaiting approval. What has been more heartening, is that we have total 256 products under development between the two facilities. So that should give you an idea as to how the future is going to pan out with this rich pipeline of products which is getting ready, with 163 awaiting approval and 256 getting into the pipeline.

We have spoken about our journey. I think we have been continuously traversing this nexus of complexity where our risk will slightly go up but rewards will substantially go up and you know in business where you have risk, you have rewards. And if you see the chart in front of you, you would see that our journey is defined in the chart starting with Oral Contraceptives. On the right hand side of the chart, you see the total market potential that one is trying to address through this effort and on the left you see the various components of this effort that together constitute riding the wave of complexity as far as the business is concerned.

Starting with Oral Contraceptives where we have 21 products in the market, 10 are pending approval. Moving on to Ophthalmology, where we have 2 products in the market, 7 filings are awaiting approval and there are more developments happening; Dermatology, as I said a while ago, we have 1 product from Gavis portfolio and 24 filings, further development is ongoing. And on to Controlled Substances, which is again a very cohesive area for business and we started making efforts in Injectables





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last two years. We acquired a R&D facility in Netherlands in the name of Nanomi and between LRP, that is Pune facility and Nanomi, will be developing a set of Complex Injectables. We set up this R&D for Inhalation in Florida, which has already made 2 filings; 1 MDI is under clinical trial and we hope to commence trial of the DPI device during this year. And then of course we have a Biosimilars program in India, where we have 10 products under development and one of them Etanercept is entering Phase-III for Japan. And of course, we have a program on new drug discovery where we have 10 new chemical entities, 4 of them are in clinical trials currently.

Talking about Global Footprint: I think very rightly we have today manufacturing facilities, 12 sites in India, 2 in Japan, 1 in United States, 1 in Mexico and 1 in Brazil. We also have a research facility in Pune in India. Also, a small research facility in Aurangabad to augment the Generic development. We have research facilities in Japan, one for Injectable, one for Oral Solid Dosage. We have R&D facilities in Somerset and we have also small R&D facilities in Mexico and in Brazil and of course Nanomi in Netherlands. So that's truly the mark of a global footprint where we have multiple manufacturing organization and multiple research facility to really pool into overall effort of moving up the complexity chain and reaching our target that we have set for ourselves.

I said in the beginning that the rigor of inspections have gone up from FDA, for good reasons, at the same time, I think -- for example, - last one year we have faced about 12, so -- and there have been times when two sites are being inspected at the same time, so that would just tell you as to how much extra vigilance is happening in -- on this count. We have had a very good record as far as compliance is concerned since 2009, but in the recent past, yes, we also face the heat as I mentioned earlier. The major among these observation has been only Goa where we had a repeat inspection from the FDA, we have responded to the observations and we have provided an update thereafter which is kind of in regular good order and we are now working for a holistic transformation. In a matter of speaking, the transformation is never complete here because the goal post keeps changing, so you have to continuously work to keep on the effort and if at all there is any failing, it is our own failing to live up to certain speed of the target changing. From time to time the prescription from the FDA undergo change, the new employees come, the training needs -- need to be augmented and therefore there are times when one has challenges to face, but we are very confident that we are going to be able to deal with it like we did it in the past in 2009. So that, kind of gives you a snapshot of how Lupin today stacks up to the trends and the challenges, as are presented to work in the industry.

Now, a quick Business Update for you: Ramesh has already shared this with you, you have the results with you I think, Q4 has been an epoch making quarter for us. It is a record turnover of Rs.4,000 crores plus and a record net profit of Rs.800 crores



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plus. Obviously, this is riding on major contribution from United States apart from other geographies like India and Japan which have also turned out very good performance. In fact, what is heartening about Lupin is that all geographies have turned out good performance, notwithstanding FOREX pressure in the emerging markets where the local currency has been depreciating, but since US is a lion share of our revenue, obviously, what happens in the US affects our overall results rather more penetratingly either in other geographies.

In terms of the annual results, as you know that we started off last year, the first two quarters were under challenge. We spoke about the price pressures in America, we spoke about the NLEM effect you know the price reduction there and in face of all that, we never had any new products in the first two quarters, so one of the ways to combat pressures of prices is really to be able to launch new products, but unfortunately, we had pretty dry spell in the first two quarters, it was from Q3 onwards that we started, you know, getting better; we did a reasonable job in the Q3, but Q4 has been fantastic.

Overall, the year witnessed a very moderate growth of 8.7 % in the top line. The net profit appears like recording slight decline of 5.5%; however, we maintain the PBT despite a severe hike in our R&D expenditure. As Ramesh was mentioning to you that this 28.8% EBITDA that you see here is, you give cognizance of the Rs.500 crores extra expenditure that we have done in R&D which is again done for the future, so there is no concern on that account because this is all going towards building IP for the future in terms of clinical development product, but just for the sake of a perspective, if that were to not to be spent, the EBITDA margin will be 32.4%, as against 30.6% of previous year, that will all flow into the PBT line. Adding to that with our unsold inventory and the tax paid on that, our tax rate has been 5% higher than previous year. So all that put together, reflects into what you see is the net bottom line of the company. It is not to justify, it is just to share with you some of the real happenings in the business.

Now, talking about some of the Major Geographies -- US: The overall business has shown a growth on corresponding quarter as well as on sequential quarters; 54%. And, this is all in dollar terms as you see on your screen. And as I mentioned that because the first two quarters were absolutely dry for a new product and we've done a lot of bucking up in the Q3 and Q4, the year ended up in US as flat.

However, there have been some remarkable achievements in the US, as you know that Lupin is a supplier of four of the top ten most commonly dispensed products in United States, we are #5 by Prescription in the US, we have a very handsome pipeline of products as we spoke a while ago with 343 ANDA filings, of which, you know, 180 are approved and Somerset facility has substantially added to that particular portfolio.



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We had 39 approvals during the year, of which 25 were for Lupin and 14 from Lupin Somerset.

India: The overall growth has been 14%, this is including the Generic business that we do, if you look at just the brands I think we grew 17% during the year, we are 8<sup>th</sup> in the India business. In the derivation of the trends we said that the way to deal with India business would be to increase our coverage of the doctors, penetrate deeper and in pursuit of that I think we have added 1,000 medical reps during this year and we have launched 5 new divisions just to make sure that we are able to pay right amount of attention to detailing to the doctors and also increase our base of doctors. So while we continue to grow and do well in India business we are also very conscious of the fact that we need to improve on our penetration and coverage of doctors and that's one of the key drivers of our growth. Apart from that, as I said, we would also be going deeper into the alliances and we've already created and we've had some very good traction on the product that we have in-license from these alliances. We launched about 19 products last year. We have been able to successfully make 60% of our portfolio as Chronic which hitherto towards very predominantly Acute Illness portfolio.

Japan: Despite all the pressures has grown 6% over the year. It is 9<sup>th</sup> largest generic company. You know that it's a strong company in CNS, Cardiovascular, and Gastroenterology. We're actually building a new dedicated site for Oral Solid Dosage, also there is a new Injectable line coming up in Japan. In Japan, it is material to have a relationship with national distributors, 4 of them, we have recently got into an alliance with one of the national distributors, we only do some business with 2 of them I think we are now trying to expand on our exposure at the national level. This should augur very well for the company in terms of getting a larger share of the distribution piece.

In the rest of the businesses also, as I said, Lupin always has this positive side that we are able to have a secular growth in all our markets. And this is even more meaningful here that what you see on the slide that whatever you see here is despite a pressure on the foreign exchange devaluation in most of the emerging markets. South Africa business has grown 10%, it is the Fourth Largest Generic Company as I mentioned earlier and the #1 Cardiovascular Company. Philippines had a fantastic record of growth of 42% as against industry growth of 9% and is ranked 22<sup>nd</sup>. Latin America— our Mexican company Lab Grin is the 2nd Largest Ophthal Company by Volume but the 4th largest by revenue. And Brazil, which is Medquímica, is rather new in our system, so we have just to see as to how it mops up, we obviously have plans to grow that business. Europe did well this time; Hormosan, which had been giving us some concerns at times was rather going up and down, we definitely see very clear signs of turning around, it's now making profit and as I mentioned earlier,



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we also have acquired a company Temmler which adds to the CNS portfolio of Germany.

API business is the strong pillar for Lupin because it feeds all our formulation endeavors. We've had a certain slowness in the growth because we have an old portfolio but a lot of new initiatives have been taken in API in terms of adding new line of therapy, new line of APIs, those are going to mop over next two to three years.

What is even more heartening that now the API business is going to participate in advanced markets, as you see here, there are 172 US DMF filings, 16 of which were made in this particular year and once they come up, you obviously see a high quality business being added to this portfolio, so that should augur extremely well for the API business of the company.

I think we have spoken about R&D that as we move up the complexity curve, I think there is little choice, but to put in more money in R&D, because as you get into the world of Complex Generics and Specialty, Biosimilars, New Drug Discovery of course, there is a lot more clinical development that we have to do and that takes in a lot of money. So as you would see that over last year -- in this year-- our R&D expense has gone up by 3%. Just in Q4, the R&D investment was 12.5% of our sales, but you also saw the pipeline that we are developing for future and it takes all that to really be able to bring that to reality. At the same time, I think one is very conscious of the fact that when we are investing in R&D, we need to make sure that our research pipeline really delivers. We continue to invest a lot of money and time in building a good pool of people in addition to what we have in India, as you know now, we have also very strong R&D in United States and the other geographies, where we today have acquired businesses. We've already shared the pipeline, so I'm not going to repeat that here.

So, having looked at the industry trends, having shared with you as to how does Lupin stack up to those trends, then a quick pen picture of how the financials have come through over the time is now you know -- is now to leave you with what are we going to be doing in the company and you see some of the key buckets here for our future endeavors. Very clearly, in Generics, I think we have to grow US and Japan by new launches and grow base business, increase penetration in emerging markets, that's very clearly the objective. When it comes to Specialty, we have to continue and reinforce our effort to build Specialty both organically as well as inorganically and we are in the process of building a Specialty pipeline. As far as R&D is concerned, I think the task is cut out because in Pharmaceuticals business there are two drivers -- key drivers of the business. I sometimes like to add the third one. The R&D on one hand, Marketing the second and maybe Operational Excellence which becomes overriding, rest everything else is a Service function if you really look at Pharma. So R&D is a



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lifeline of our business and we will continue to deliver on the pipeline and we will evolve the Complex Generics and Specialty pipeline over time, the effort has already started showing up, you will see that in coming quarters. I said that a while ago Operational Excellence, Cost Leadership, High Efficiency, Optimal Time Cycles is the order of the day. You have to remain lean and I think that's what our endeavor is as far as operational excellence is concerned. Compliance is going to remain a major challenge in our business and we all understand that if you've hooked for non-compliance, what it can cost you and therefore that would always remain an area of high interest.

With that, I come to an end of my presentation. Thank you very much.

I think we can now take questions and we will deal with the questions as they come. Do you have some? Okay, Alpesh is saying that we will have questions from the live audience and alternatively also with the connected audience.

**Moderator:**

Thank you. Ladies and Gentlemen, we will now begin with the Question-and-Answer Session.

**Prakash Agarwal (Axis Capital):** Hi! Thanks. First question to Vinita. This is Prakash. On the US business, so great show. Just trying to understand how the base business has performed because clearly we had this opportunity of Fortamet, then Glumetza, so -- because we've been hearing a lot of global generic companies talking about a lot of erosion in the base business. If you would highlight how much would be the growth in the base business that we have seen in the quarter?

**Vinita Gupta:**

The base business was pretty much flat, if you take Fortamet aside and Glumetza aside, the base business the volume was up, pricing was down a little bit but in terms of what was heartening from our perspective was the previous year we have seen a strong double digit price erosion, in the fiscal year '15 we have seen (+20%) price erosion, in the base business we saw single digit price erosion at this point and we think based on all of the events that have taken place already, all the consolidation that has happened, but for -- I mean, this week we had McKesson and Walmart which we hope is going to mean some upside for us, but majority of the investments having happened, we believe that the price erosion, price pressure in the US market, the pricing should stabilize at this point. And prior to this consolidation phase, we used to see a single digit, mid you know 4, 5, 6% price erosion, we see pricing getting back to that kind of dynamic.

**Prakash Agarwal:**

Could you share the outlook also for the year given that we are yet to see approvals from Goa facility?



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**Vinita Gupta:**

Yes, so a good part of the growth for the fiscal year '17 is Glumetza, the product that we just launched, we see significant upside in fiscal year '17, Fortamet, again, should be a significant contributor to fiscal year '17, both products we expect limited number of competitors, Fortamet, we have one of two right now and we think over the next 12-months – 24 months we probably see one or two additional competitors, likewise for Glumetza, we see two competitors coming in after our six-month exclusivity is up in August, but we still think it would be a sizeable opportunity for us and as the rest of the industry. So good part of growth for fiscal year '17 is our existing portfolio and then the new product, we certainly are looking forward to new product approvals despite our challenges at Goa, we hope to be able to resolve the 483 with FDA. Proactively we have started tech transferring the materials products that we expect to launch in fiscal year '17 to our other approved sites to Indore to Aurangabad and to Somerset. Then, we go through the Gavis portfolio, then we have a very nice site – Generic portfolio that we have added in March with the acquisition of Gavis, we see the potential of expanding share on the Generic side of the portfolio, Gavis had a reasonable share but we have stronger reach, stronger relationship with the customers, that should enable us to expand share. And lastly, the growth on the Brand side of the business, the last year – last -- last year was really challenging for our Brand business, we saw Generic Suprax right at the start of the year – you know in April that for us our whole Brand business down significantly to \$45 million this last year. When this year with the restructuring of our commercial infrastructure plus the addition of two products – our Gavis and particular Methergine – we see the Brand business getting back to a reasonable level of revenues. We had two products as Dr. Sharma mentioned Methergine and chewable Methylphenidate that Gavis was sole source on that we believe could benefit from promotion. So, we took our sales force 120 people from Pediatric, Primary Care split to Pediatric Women's Health and Primary Care and have started calling on the hospitals of kinds with Methergine, and they have got very good initial response. Likewise, we added Methylphenidate, chewable Methylphenidate source on to the Brand side, the Pediatric portfolio and have started promoting in and again we started seeing a ramp up scripts with chewable Methylphenidate. So really I mean a lot of our growth focus is the products that we have launched in the last year, the products that we have acquired and there is opportunity on the Brand side of the business that we leverage out of the Gavis portfolio and new products additions out of India as well as of Somerset.

**Prakash Agarwal:**

Thanks. And second question for Ramesh, those two accounts there was mention of about 45, 46 billion, billion worth of intangible because of the Gavis acquisition. So, would this be amortized over 10-years given the fact that normally amortization happens?

**Ramesh Swaminathan:**

Gavis this time by around what we have actually amortized is a very small increase this quarter itself which is about 25 to 27 crores which actually came from Temmler



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and a part of Gavis. But you are right about the Gavis intangibles being amortized that will happen next year because that's going to be the full year that we are holding and it's more under the IFRS standard itself and you'd be looking at a substantial amortization next year for sure.

**Prakash Agarwal:** If I get the numbers right, I mean, current depreciation is about 450, 470-odd crores is expected to double, is that correct understanding?

**Ramesh Swaminathan:** Yes, that would be correct, there will be a fair degree of amortization happening.

**Moderator:** Thank you. We'll take our first audio question which is from the line of Ranvir Singh from Systematix. Please proceed.

**Ranvir Singh:** R&D expenditure, I wanted to understand what would be in terms of percentage of sales in FY'17?

**Nilesh Gupta:** So for the last year we are approximately at 12% of sales and R&D spend and we believe that it'll be somewhere between 12 and 15 for – for the FY'17 period. The main increase is coming from lot more filings, so for example, last year we filed 36 ANDAs that is you know pretty high -- pretty up there in the industry when there is a similar run rate that we're expecting in -- probably more as a combination of Lupin and Gavis. We are also getting deeper into the investments on innovation, so we have at least two clinical trials that will begin in the financial year, we are deeper in Dermatology, we are deeper in Biosimilars, so we expect to pretty much complete the intensive clinical trials in the financial year and then we are investing in Drug Discovery as well. So all of this together, probably IS going to take it somewhere between the 12-15% -- within 15% likely more than 12% in terms of R&D spends.

**Ranvir Singh:** And of what proportion would be on Biosimilars?

**Nilesh Gupta:** So Biosimilars somewhere between 7<sup>th</sup> or an 8<sup>th</sup> of the total spend.

**Ranvir Singh:** Okay. Second question is related to India business. So, can you give some indication as to how this FDC-related issues impact our portfolio?

**Nilesh Gupta:** So I think the – you know Shakti and Rajeev are here, but the market in India is hostile at this point, it's pretty challenging environment and we are very proud of the fact that we grew by 15% in this period. Couple of things happened, a lot more of our products have come under NLEM as have for the industry as well, but almost 24% of our portfolio is now under NLEM and that as a fact that the WPI is negative, doesn't have and then or add to that the FDC ban. Obviously, we have got to stay at this point, we don't know how things will transpire and what timeframe they transpire in but the





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government is slowly talking about more products coming under an FDC ban as well. Amongst all of this so there's lots of challenges, but as you saw in Q4 we added 1,000 reps, we added 5 divisions, we still see growth coming out of India, and my estimate is that in FY'17 we will probably grow by 15% again.

**Ranvir Singh:** And the new MRs, how this has been allocated among divisions, this is all related to that 5 new divisions?

**Nilesh Gupta:** Yes, most of these are related -- in fact, all of these are related to the 5 divisions, basically we had too much brand load on a lot of our big divisions like Inhalation and Metabolics and we have split those divisions, we split brands out as well and the intention is to build big brands.

**Ranvir Singh:** That's it from my side. Thanks a lot.

**Neha Manpuria:** Neha Manpuria from J.P. Morgan. On Gavis, you reiterated 2016 revenues for Gavis, which was our initial guidance. Given a lot of commentary in the US is coming on Controlled Substances and Derma, two areas where Gavis is focusing on, are we still confident achieving the tripling of revenue in Gavis? And second question, you had given a long term revenue guidance in the past. So, how should we look at that -- has that changed or would you reiterate? Thank you.

**Vinita Gupta:** The Gavis guidance of tripling our revenues based on our experience in the last 2-months you know having closed the transaction we believe we are on track in this year it's going to tell, but we certainly believe based on the initiatives that we have executed both on the Generic and the Brand front that we are on track. They have good number of applications that they've got approval for the past year, not all of which have been launched, so we expect this year to be a significant year out of Somerset for the organization. On the longer-term aspiration that we have shared you know the fiscal year '18 aspiration now it doesn't look like it's that long-term, it's year -- next year after this fiscal year we believe based on the initiatives that we have executed on the acquisitions that we have made organic growth efforts, the pipeline that we have for the US, Japan, India, other parts of the world that we can get to \$3.5 million or thereabout, I mean, our aspiration was certainly to get to \$5 billion but we think based on the current market scenario in the US on the Generic side of the business, based on what we have seen in the emerging market with currencies that we will likely get to \$3.5 million where we sit right now. Of course, as we continue to work on other inorganic efforts in particular to build a Specialty business, first, that is what we -- what we see right now, we still have an aspiration to grow beyond that, but we think it's probably till we -- may be a year after or 2-years be on fiscal year '18, and like Dr. Sharma said that we have never been on the mind set of acquiring to gain scale, you know, our effort has been to gain capabilities and strategically to our





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business, we will continue to be focused on driving efforts both organically and inorganically to get to that \$5 billion number as soon as we can, but through efforts that – that meet our strategy – that fit our strategy.

**Mr Rakesh Jhunjhunwala:** What percentage of R&D expenses goes for NCEs?

**Nilesh Gupta:** So very similar to the bio-similar numbers, about 6<sup>th</sup> of the spends would be on NCE, and then that also includes overheads and everything else which we would have a common R&D spend. We were hoping to license out our first NCE last year that didn't happen and we've obviously been getting pretty deep into conversation, so there has been some near misses, but we have three products that we are talking to potential plans, potential targets at this point of time, there is one product which will finish clinicals in this financial year -- there is probably another one which will also finished towards the end of this financial year, those will give us two more opportunities to license out, but I don't think they will happen within this financial year in FY-'17, but in FY-'18 we are looking at, at least three assets out of which we should be able to license out. So, I would personally be very disappointed if we don't license out in FY-'18, but the goal that we're seeing right now is to still try and license out in FY-'17.

**Sameer Baisiwala (Morgan Stanley):** Hi! Good Evening. Just on Gavis. Earlier your expectation was that this would be EPS-accretive from the year one. Does that still stand and does that include amortization charges or without that?

**Ramesh Swaminathan:** Yes, it is going to be EPS-accretive and even despite the amortization charge you still be in that EPS-accretive.

**Sameer Baisiwala:** Great. And the second question is what's your top line growth expectation and margin expectation for fiscal '17?

**Nilesh Gupta:** Ramesh, can we tell that we don't give guidance

**Ramesh Swaminathan:** We don't give guidance for sure. Can we take the comments from Dr. Sharma?

**Dr. Kamal K. Sharma:** I think my -- Sameer, my saying would be Sameer that we will have a robust performance as we've been doing and notwithstanding some challenges along the way which are part and parcel of the business, but we see a promising year ahead, that's all I can say.

**Sameer Baisiwala:** Thanks.



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- Manish Jain:** Manish Jain here. Just wanted to get an insight on the Inhalation side on that Nilesh you referred to, what's the kind of expenditure you want to invest, make in fiscal '17 on the clinical trial?
- Vinita Gupta:** We have three programs in clinical development in fiscal year '17 potentially, then we just 1 meter dose inhaler Albuterol and 2-DPI. So it would be a significant part of R&D investment for fiscal year '17.
- Manish Jain:** Thanks.
- Alpesh Dalal:** We will take the next question from the audio participants.
- Moderator:** Thank you. The next question is from the line of Gaurang Ved who is an individual investor. Please proceed.
- Gaurang Ved:** Thanks for an opportunity. Sir, just want to check that earlier you had given a guidance of \$5 billion and now you are saying roughly your endeavor will be to reach \$3.5 billion and your endeavor was to hit the 20% net profit margin. So, sir that guidance still holds or we have to scale it down considering that you are guiding for an R&D expenses in the range of 12% to 15%?
- Nilesh Gupta:** The net profit guidance remains the same, I think we are close to those kind of number, I think it will stay at 20%.
- Dr. Kamal K. Sharma:** I think if at all we are relenting on the top line and this is a favor of ensuring that the bottom line stays as we had earlier planned, so emphasis would be in doing high quality business and keeping the cost under check. So you can see a fairly steady achievement as far as the bottom line is concerned.
- Gaurang Ved:** Fine, thank you, sir, and all the best for your future endeavor.
- Aditya Khemka (DSP Blackrock):** Aditya here from DSP. Just to pick your brains on the US business for the quarter, we understand that there were two large products, right, so and we understand you wouldn't like product-specific sales, but ballpark top-5 products, what is our product concentration on the US business in terms of revenues – top-5 products, how much would they be contributing to the revenues for the quarter?
- Vinita Gupta:** No, we don't have it, but we can get it to you.
- Aditya Khemka (DSP Blackrock):** Okay, that would be useful. Secondly, on the Gavis front, so as Ramesh you mentioned that it would be EPS-accretive. Would it be the same story on the cash flow front? Would Gavis require further investments in terms of CAPEX,



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in terms of more high ringier of spine test or whatever R&D CAPEX or capacity CAPEX?

**Ramesh Swaminathan:** There would be of course investments required at Gavis that will be for their own – it's not going to be a substantial for sure, there'd be R&D spends, there would be of course capital expenditure, because there is a plan that we could expect that to be nominal in our scheme of things.

**Rakesh Jhunjunwala:** Okay. **Your tax rate will be lower** going forward?

**Ramesh Swaminathan:** Yes, that's correct – that's correct, but you have structured it slightly differently, so to that extent we would be in a position to take some look at a lower tax rate for Gavis operations alone.

**Rakesh Jhunjunwala:** This year even after the R&D spend, we have full tax of 34%. So I was wondering for the full year not for the quarter.

**Ramesh Swaminathan:** That's correct, that's because of the accounting standards in India because when we actually transfer products into the US from out here and if it remains as unsold inventory, we got to account for the taxes but to take it to the P&L whilst the top line and the revenues are not there.

**Rakesh Jhunjunwala:** Every year it affects, no?

**Ramesh Swaminathan:** Next year it will not be the case because we are moving on to IFRS, because of the new standard.....

**Rakesh Jhunjunwala:** The amortization of Gavis, that will be not be tax deductible, is it not?

**Ramesh Swaminathan:** Well, it's on the consolidated accounts you are talking about the amortization, but the way it is being structured we also have in fact it's been structured as an asset deal, so to that extent it is possible to take amortization in the country where it is housed.

**Charulata (Dalal & Broacha):** Hello! This is Charulata from Dalal & Broacha. My question is pertaining to the debt which has gone up significantly in this year. Can you give the breakup of how much will get into capital expenditure, how much will get into R&D from this?

**Ramesh Swaminathan:** We acquired Gavis for about \$890 million and bulk of the debt that you see on the balance sheet is actually going towards its outlay.

**Charulata:** How much will be the CAPEX going forward?



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- Ramesh Swaminathan:** The run rate in the past is close to about 1,000 crores but next year we are looking at a substantially higher amount.
- Saion Mukherjee:** Yes, it is Saion from Nomura. Vinita, when you talked about – it appears that you are looking at lesser number of launches next year in the US. So can you just share how many approvals, launches you are looking at? And of your pending ANDAs, how many are linked to the Goa side?
- Vinita Gupta:** So we're looking at roughly around 25 to 30 launches, 15 out of Somerset and another 15 out of India. In terms of the products, the filings out of our sites in India, the majority of the pending applications are actually from Pithampur from Indore, but roughly 30% of our filings from Goa
- Nilesh Gupta:** So we have about 100 filings pending approval and about 30 of them are the ones pending from Goa.
- Saion Mukherjee:** And in terms of your communication with the FDA on the Goa side after the inspection, I mean, do you have any idea of whether it is just a classic side of the OAI or VAI and when do we come to know that and is there a risk of a warning letter therefore?
- Nilesh Gupta:** So we don't know the classification that the FDA is going to do for the site, very often you will get to know only after they have made a determination, they haven't made a determination at this point. We've sent an update – we've sent a response and then we sent an update and we've talked about a lot of the enhancements. We are doing a major initiative... we actually started it 2-months before we started it in February across one of our biggest API sites, one of our biggest Formulations sites, the Formulations site was Goa. So we have started a lot of things but I think in light of the 483s, we certainly have aligned a lot more into what we feel we need to do. Hard to say at this point whether it would go into a warning letter or not, but one of the things that we're doing in terms of moving pending applications is obviously even preparing for the worst if that were to happen.
- Saion Mukherjee:** For site transfer, what does it take like for the products which are not yet approved, if we do a site transfer, do you go back in the queue or proceed with the same – I mean is there any implication for the timelines to approval?
- Nilesh Gupta:** This would be an amendment that the FDA would allow in the review process. Batches, stability, if it's an extended release product then bio studies as well and we would submit with that.



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- Saion Mukherjee:** So for all your key products, right, which you are doing site transfer, when will you be able to – I mean, do you need to do biostudies for all of them or for most you don't need to do?
- Nilesh Gupta:** So there are blends, not for all of them, but we basically in the next -- so we already started the process and basically by the end of June we will have completed pretty much all the site transfers that we want, and in another 3-months after that we will have filed them.
- Saion Mukherjee:** So I mean whatever your initial timelines for approval that has a change material is what you are saying?
- Nilesh Gupta:** It will change – well, there is at least a 6-month delay in some of them, some of them were obviously further out, so those we are not even going to bother moving, so it's not all the products that we are going to move.
- Alpesh Dalal:** Next question from the audio participant.
- Moderator:** The next question is from the line of Sangam Iyer from Subhkam Ventures. Please proceed.
- Sangam Iyer:** Hi! Sir, two questions from my side. The guidance of \$3.5 billion that you gave, does it factor in any further inorganic initiative?
- Nilesh Gupta:** No further inorganic initiative in that 3.5.
- Sangam Iyer:** Okay. Secondly, the effective tax rate that we've mentioned, I mean it was not audible on the call. How much are we looking at for FY17 and going forward?
- Ramesh Swaminathan:** The tax rate would be lower than what it is today for sure, we would imagine this between 28% and 30%.
- Sangam Iyer:** Okay. And finally, Q4 we saw the working capital getting a bit stretched. Was it more Glumetza launch effect or is there Gavis phenomenon here, I mean, what could be the normalized working capital that one should look at going forward?
- Nilesh Gupta:** Ramesh, the working capital do you see in normalizing or do you see it remaining at the Q4 level?
- Ramesh Swaminathan:** The working capital this time around has gone up quite a bit only because of the fact that there was this Glumetza launch and a lot of it is actually in the form of accounts receivable because it is all February and March, so it is not realized, but we do expect



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it to come down, inventory is also -- it is essentially in anticipation of stocking up for that situation. So, we do expect it to come down you know in the first quarter itself.

**Sangam Iyer:** Great. Okay. Thanks a lot and all the best.

**Alpesh Dalal:** Any more questions from the floor?

**Anmol Ganjoo:** Yes, Hi! This is Anmol from JM Financial. In terms of the incremental R&D spend that we have had this year, if we were to break it down across buckets, would you like to break this 500 crores incremental number that we have had, how would you characterize it, what the breakdown like on an annualized basis?

**Nilesh Gupta:** So I don't think we have a bridge right now, but I think directionally I think the big increases would be across Inhalation and Biosimilars.

**Anmol Ganjoo:** On Inhalation, I heard some commentary around potential FY'18 launch. Would you like to talk a bit more about that, what is the pathway, in which markets to be a growth for us?

**Vinita Gupta:** The first market of focus for us is the US and you know last year we filed our first Nasal Spray, this year we are hoping to file our first MDI, you know, that would be the first launch, and in the next year we would expect to file DPI potentially Advair what we file in fiscal year '18, so potentially will be launched and in fiscal year '19, so probably earliest calendar year '18.

**Participant:** My last question to Nilesh. Nilesh, you spoke about a massive overall in response to some of the regulatory events that has happened. Would you like to put a cost around it in terms of will likely to be in 12-months?

**Nilesh Gupta:** So not so much because I think a lot of the issues that we've seen at Goa are really about people not following SOPs as they lay down for example, it's not whether the SOP itself was adequate or not, it's different from the way we've written it down and those are some of the observations that you have seen. So on that level I think it's a lot more about simplifying and we are working with outside consultants on that, we are working with pwc, we are also working with Lachman on this, we are also working on the culture fronts McKinsey and -- on that but all of this is not particularly big spend, in fact, some of those variations will cost more than some of this. What we are trying to do in the longer term is for example we want to be able to add a software layer so that any out of spec anything gets automatically highlighted to management and some of these systems don't exist, those will probably be more expensive but these are going to be pilots and we are working with certain partners to actually develop



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this as a platform for us. So I don't really see a very meaningful increase in spends on this count.

**Alpesh Dalal:** Next question from the audio participant.

**Moderator:** Thank you. The next question is a follow up question from the line of Ranvir Singh from Systematix. Please go ahead.

**Ranvir Singh:** Yes, thanks for follow-up. I just wanted to understand the debt -- whatever debt we see, the incremental debt is on Gavis, what would be the amount?

**Ramesh Swaminathan:** Incremental debt is extensively because of Gavis -- the acquisition itself, the amount is close to about 6,500 crores odd.

**Ranvir Singh:** And given that now our debt-equity ratio has already come in more than one. So what I wanted to understand despite not having any acquisition going forward that \$3.5 billion of target will come from which geography or which segments -- in major segments if you could highlight something?

**Ramesh Swaminathan:** The first bucket is about -- first question is about in fact the debt-equity ratio. It's about 0.56 currently and **incremental revenues will be coming from a lot of markets**, but US of course would be the biggest driver.

**Ranvir Singh:** Okay. So that implies roughly 30% CAGR. So that would be on organic growth from US?

**Ramesh Swaminathan:** Yes, so our internal exercise that indicates that the pipeline that we had built over the -- assiduously over the last several years is pay off and that's where we expect this growth to come from.

**Ranvir Singh:** Okay. Thanks a lot, sir. All the best.

**Dr Girish Bakhru (HSBC):** Vinita, on 25-30 launches in US, are there any FTF in fiscal '17?

**Vinita Gupta:** It's a couple, I mean, like we just launched Intermezzo out of Gavis and we are first-to-file on it, we expect **Minastrin** to launch early -- mid in the year.

**Dr Girish Bakhru:** Anything for Gavis?

**Management:** Intermezzo from Gavis.

**Dr Girish Bakhru:** Not any more, right? Suprep?



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- Dr Sofia Mumtaz:** No other first to file for Gavis. Suprep it's later.
- Dr Girish Bakhru:** Thank you.
- Rakesh Jhunjhunwala:** **You have converted two generics in which you were sole players as brands.**  
What kind of profit and what kind of volumes they bring?
- Vinita Gupta:** So we are hoping when we are working towards trying to get the brands in this close to peak revenue this year, we will see, I mean, it's early days right now, but a combination of our restructuring efforts on the commercial front as well as the addition of Methylphenidate as well as Methergine we hope to get it back to \$100 million plus figure. Paul, would you like to add to that?
- Paul McGarty:** So, as far as the potential for Methergine product that product in itself could be our largest product
- Vinita Gupta:** Methergine is a brand product that can afford the investment of the commercial infrastructure. We really see a potential obviously in that brand, I mean, it was -- it's the only product for the indication for postpartum hemorrhage, there is nothing else, and the product was not promoted for many years, so the molecule was declining, and through our market research we found out that if we would promote the product, we can potentially grow it. So, this is another few facts for us the way we look at it one that will help us build of its health portfolio franchise.
- Chirag Dagli (HDFC Mutual Fund):** Hi! This is Chirag here. We saw in the presentation two of your facilities got repeat inspected in a year. is it Lupin specific, is this an industry trend, is this a new thing that the FDA is doing, does this have any bearing at all on the eventual prescription and the fact that there were repeat observations you know, does it have any bearing on the OAP resolution would work?
- Nilesh Gupta:** So Goa itself got inspected twice that we know that the second one was -- actually it was actually classified as a pre-approval inspection for certain products when they came in, but they've also ended up reviewing the earlier. The other repeat inspection that you probably saw was for Indore. What we have done at Indore is that we have actually -- we have three registrations in Indore, it's actually not considered one location as far as the FDA is concerned and that's why the FDA would come for each of those, so they came for if I am not mistaken all three in the last 18-months or certainly for two and then probably come for the third one as well. In the Goa observation itself, while at the face of it some of them seems similar to some of the observations, there are no repeat observation as such. Pointedly, if there were repeated observations we would have been pointed out as such obviously they were by the classification some of them fall in similar bucket, stuff like cleaning or validation





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processes and adherence to SOPs. So I think there are some commonalities, but there are no repeat observations and I think that's a good thing because the FDA would have not been happy if they saw repeat observations coming up on the same things that they had pointed out before.

**Chirag Dagli:** Thank you.

**Krishnendu Saha (Quantum Asset Management):** This is Krishnendu. Just a little bit of understanding on your outlicensing. When you propose to outlicense a couple of them in the next year or so, what do you expect, \$50 million or \$100 million, what do you expect from that, some light and what phase you expect to outlicense?

**Nilesh Gupta:** Raj, why don't you answer this question.

**Dr. Rajender Kamboj:** So the highest value in selection for outlicensing is that we have clinical demonstration in the patient and that's where maximum return for the partner is. Presently out of the four products, we have three products where we are seeing translation in the patient or improvement in end-point. The trials for completion for some of them will take all of the current fiscal, but one of the programs which we are in active discussions with multiple partners interested, in that program, we have parked that program so that we don't delay the potential partnership. I am very confident about the product, this product already has translation, and when I say translation that particular product is in chronic kidney disease and bone metabolism, there is only one product ever approved globally and this product is a very differentiated product, not been a follow on addressing much larger population. So we're very actively looking for – for that product and we have already demonstrated translation in that product for the final approval end point. So we are optimistic, but these things require longer than anybody can estimate and these are highly innovative addressing very large market size opportunities.

**Nilesh Gupta:** So typical upfronts would be of the order of \$25 to \$50 million usually for Phase-II asset, I think it depends on the kind of clinical activity that you show, one of the lead compounds that we have within the CNS space if that comes out successful that is a very valuable program.

**Krishnendu:** You spoke about what therapy, did you speak about therapy in that?

**Dr. Rajender Kamboj:** Chronic kidney disease, it's a kidney failure so there is an underlying pathology of what is called hyperparathyroidism, so there is a primary nature related to bone, and in the kidney failure is the secondary hyperparathyroidism.

**Krishnendu:** For Phase-III?



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**Dr. Rajender Kamboj:** No,- we have completed Phase-I but we have demonstrated in the Phase-I a very high translation of the primary end point which is the approvable end point for the final product already demonstrated in the Phase-I. So once the translation happens the risk for product development is significantly reduced.

**Moderator:** Thank you. Ladies and Gentlemen, on behalf of Lupin that concludes today's conference call. Thank you for joining us and you may now disconnect your lines.