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# Lupin Ltd

## Get in the loop

Lupin Ltd is future ready for making big strides in regulated pharmaceutical markets. It has the largest capacity of approved plants in India, a few product approvals and patents, and a pipeline full of lucrative products. It has already started selling in these markets and the momentum will pick up going forward.

**Buy Price Rs.196 Appreciation Potential: Substantial**

The stock currently trades at 10 times trailing consolidated EPS (Rs.19.30). We expect its earnings to grow substantially not only due to high growth from regulated markets but also from a strong position in non/semi-regulated markets on the back of scale economies and market dominance.

### Key Data

Market Cap	Rs.7.9bn
Shares Outstanding	40.1mn
52 week High-Low	196 - 90
Average Daily Volume (BSE+NSE 12 months)	541,224 shares

### Shareholding %

Promoters	67.22
Institutional Investors	4.54
Others	28.24

### Major Shareholders

UTI	2.60
Rekha Jhunjunwala	1.26
Rakesh Jhunjunwala	1.00

### Stock Performance

3 months	+29%
6 months	+98%
12 months	+73%

### Multiple Valuation

<b>FY03</b>	
EV/EBIT	10.1
Market Cap/Sales	0.65
P/E	10.2
P/BV	2.2

### Key Investment Points

- Lupin is global leader in anti-TB drugs with world market share in top three drugs in 40-80% range.
- Lupin is lowest cost integrated producer of Cephalosporins, the fastest growing anti-biotics.
- Alliances with APA, Merck Generics, Yuhan and CKD.
- Long pipeline of generics – both APIs and formulations
- No major capex in near term
- Strong team of professionals in place

### Value Kickers

- A product pipeline full of promising generics and a few NCEs under development may throw surprises
- Realisation of money lent to group companies

### Party Poopers

- Lupin has highly leveraged capital structure. This puts Lupin at a strategic disadvantage. Capital structure needs to be optimised.
- High sales receivables (113 days of sales and 50% of debt) need attention.
- Regulatory, legal or technical hurdle in the launch of products planned for the near term may bring in temporary weakness.





## Brief Business Profile

Lupin Ltd, a Mumbai-based company with consolidated revenues and PAT of Rs.12bn and Rs.780mn respectively in FY03 is mainly into Cephalosporin (50% of revenues), anti-TB (30%), and Cardiac (11%) drugs – both bulk drugs and dosages. It is global leader in TB drugs – Rifampicin (40% global market share), Pyrazinamide (50%) and Ethambutol (80%). Lupin is world's leading integrated low-cost Cephalosporin manufacturer. It has alliances with American Pharmaceutical Partners, Merck Generics, Yuhan Corporation, and CKD in Europe and USA.

## Key Investment Points

### *Opportunities in Regulated Markets*

Regulated or advanced markets of the US and the Europe present the largest opportunity to Lupin. Sale of APIs to Non-regulated markets and within India will continue to do well. Domestic formulation sales have been falling lately. Domestic market will continue to be a low or no growth market. Exports to advanced markets contributed only 9.8% to FY03 revenues, up from 7.7% in FY02. Currently it exports only APIs to advanced markets (Rs.1,088mn in FY03; Rs.728mn in FY02). Once it starts getting ANDA approvals and the approved drugs go off patent, it will sell formulations also to advanced markets.

### **Strategy for regulated markets**

Seven of Lupin's API plants have been approved by the USFDA and two plants (one formulation and one API) have been approved by the UKMCA. It so far filed 30 patents in the US (18) & the Europe (12) and has been granted 15 patents. Besides patented drugs, it also has a few generics in its portfolio. For some of the drugs, it will sell API and for some formulations.

### **Exclusivity through complexity**

Its major emphasis is on creating exclusivity through complexity. It has established an intellectual property cell, which identifies drugs that are going off patent but are complex to make. It also identifies drugs where process patents will take long to expire after product patent expiry. For such drugs, it is developing non-infringing processes. With these kind of drugs, it intends to create an exclusive market for itself.

Lupin is already selling one such product – Cefotaxime Sterile. It has a non-infringing process for this drug. It is the only generic player even 20 months after the launch.

The third way to create exclusivity is to develop an NDDS. Lupin is working on quite a few NDDS. NDDS can be licensed to the innovator if the patent has not expired or the company itself can introduce it in the market after the patent expiry and get three years' exclusivity.

Unlike many other generic players, short-term time-bound exclusivity like Para IV filing is not its prime goal. It's a short-term exclusivity and the exclusivity ends with end of the period. Exclusivity created through complexity can last much longer even without any patents.



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## Near Term Opportunities

### Lisinopril

Lupin commissioned 12 MTPA Lisinopril facility in Feb-03. It already had 6.6 MTPA capacity for Lisinopril. It will also make other 'Prils' like Benazepril and Fosinopril at the new facility.

Lupin has captured a good share of European Lisinopril API market. It has also started supplying Lisinopril API to the US. Lisinopril has 40.4% share of the US Prils market at present.

Generics have captured over 90% market share in the US. With over a dozen generic players, the market is overcrowded but is large enough to accommodate all of them. Lupin will have an edge, as its cost of production is lower due to large capacity and scale economies.

### Cefuroxime Axetil

The product patent for Cefuroxime Axetil expired in May-00. However, two process patents are pending, one each related to 'amorphous form' and 'spray drying process'. These patents expire on July 29, 2003.

Glaxo's Ceftin was the original drug. Ranbaxy is the only company so far to launch its generic. It had got six months exclusivity, which is over now. Yet no other generic player has emerged. Apotex of Canada wanted to launch the generic but lost patent case to Glaxo. Lupin has agreement with Apotex to supply the API. Launch quantity of this drug has already been supplied to Apotex.

Apotex and two other generic companies (one of these is Geneva Pharma) will now launch it on July 30, 2003. Ranbaxy had launched the drug at risk. Trial to decide whether Ranbaxy infringed Glaxo's patent is on July 8, 2003. This trial is unlikely to have any impact on launch by Apotex. Ranbaxy had \$115mn sales in 2002 from this drug. It cornered 93% market share.

Lupin has two opportunities here. The first is the opportunity to supply API to Apotex Aug-03 onwards. The second opportunity is a much bigger opportunity. Lupin has filed its own ANDA for this drug. USFDA inspection is over and the approval is expected during Jul-Sep-03. While Lupin will supply Crystalline Cef Axetil to Apotex, it will use Amorphous Cef Axetil (better than Crystalline) for its own dosages.

Lupin will also have an edge over Ranbaxy in terms of cost of production. We learn that Lupin's spray drying process cost much less than that of Ranbaxy. Therefore, though Ranbaxy has already cornered 90% plus market share, Lupin may be able to break into it on price.

### Cefixime

Cefixime is a third generation Cephalosporin and is used to treat infections of the ear, throat, urinary tract, and sexually transmitted diseases. Lupin has filed two ANDAs for Cefixime – one for Dry Syrup Suspension and another for tablet.

Global market size for Cefixime is \$400mn. The US market size is \$100mn. The US patent expired in Nov-02 but no generic player entered so far. This is another example of creating exclusivity through complexity. Lupin targeted this drug because it is complex to make a copycat of this drug. Because of the complexity, no body entered the market even six



months after patent expiry. ANDA approval is expected in next 2-3 months. Lupin will be the first to enter the market and cream it. The European patent expires in 2005.

### **Lovastatin**

Lovastatin plant with 12MTPA capacity is under construction and is scheduled to commence operations in QE Sep-03. Lupin has a long-term contract with a global pharmaceutical firm for the supply of Lovastatin API. Lupin will supply the API to multiple customers.

Lupin is currently making Lovastatin at Rifampicin plant. The company intends to make other statins like Simvastatin, Atorvastatin, etc. The global market size for Lovastatin and Simvastatin (derivative of Lovastatin) is \$6bn and Lova is the fastest growing statin.

Teva had launched the generic Lovastatin in Dec-01 and had sales of around \$20mn in 2003. Andrx Corporation has a branded Lovastatin generic called Altacor in the market. Biocon of India has USFDA approved facility for Lovastatin. The market is crowded but its large enough to accommodate number of players. Other Lovastatin brands in the US market are Mevacor, Lipitor, Pravachol, and Lescol.

Lupin's edge will be that it is setting up a large capacity and this will give it scale economies. It will be among the world's top five manufacturers of Lovastatin API.

### **Ceftazidime**

Lupin is already selling it in Europe. The US patent expires in Sep-03. The market size for the drug at present is \$120mn. Lupin is developing a non-infringing process (NIP) for the drug. Stage of development could not be ascertained. As Lupin is developing NIP, it should be able to commercialise it after Sep-03 or on product development & approval whichever is later.

### **Strong generics pipeline**

We have talked about only the near term opportunities above. There are many more generic drugs with or without exclusivity in pipeline. DMFs and ANDAs have been submitted for some of them. We expect a few INDA submissions for NDDS and improved chemical entities (ICE) and these will provide three-year exclusivity under 505 (b)(2). Last year it filed two ANDAs for Ceftriaxone Sterile and Cefotaxime Sterile. Ceftriaxone goes off patent in Jul-05. Cefotaxime is already off patent and Lupin has been selling API to its alliance partner APA since Sep-01. ANDA approval to Lupin is expected anytime. However, the launch of dosage form will not be immediately. As long as the alliance with APA works fine, Lupin will continue with it. An ANDA approval will be handy in case Lupin thinks it's not making enough money by selling API to APA. Lupin has a non-infringing process for Cefotaxime. There is no other generic player in the market.

### **New Chemical Entities**

Lupin has identified three herbal drugs – one each for treatment of migraine, psoriasis, and asthma. Herbal drugs unlike synthetic drugs do not go through screening and shortlisting process. Once a herb is identified and proof of concept established, it sails through till the end. In synthetic drugs, a molecule can be dropped off at any stage, even at the last stage.

Lupin has already filed an INDA for an anti-migraine herbal drug with USFDA. The phase-II trial will begin shortly for this drug. The company will look to license it out for further trials,



if and when it gets suitable price for it. Till such licensing possibility fructifies, it will carry on the process on its own.

The licensing of the drug can take place any time. It will imply immediate cash inflow and a certainty of cash inflow stream in terms of milestone payments and sales-linked royalty on commercialisation.

Another INDA for psoriasis herbal drug will be submitted to USFDA shortly. The psoriasis drug has just completed pre-INDA phase. After the approval from USFDA, phase-II trials will begin. For all its NCEs, the company will look at licensing out.

A herbal drug for asthma is currently in pre-INDA stage. It is also doing NCE research for a synthetic drug for TB. This is, however, at a very preliminary stage (the search mode).

### ***Strong team in place***

Lupin has, over the last 3-4 years, put up a strong team in place. It's R&D head is ex-Ranbaxy R&D Head – Dr. Himadri Sen. He was with Ranbaxy for 10 years till 1999 and had worked on Cipro OD, which was licensed to Bayer. Prior to Ranbaxy, he was in UK Pharma industry in R&D for 20 years. Dr. Arora, who was with Ranbaxy for four years, has also joined Lupin R&D. It has put experienced people with track record as business and functional heads. It recently recruited its HR head from Aventis.

### ***No more major Capex***

Lupin is through with its Major Capex program. Capex from now on will be only the maintenance capex and capex for balancing equipments. We expect asset turnover to rise significantly going forward.

### ***Skills in Fermentation Process***

Indian pharma companies mainly have skills and cost competitiveness in drugs made from synthetic process. China rules drugs made from fermentation process. Companies like Aurobindo and Orchid have set up their fermentation plants in China. Lupin has its fermentation plants in India and yet it has been successfully taking on the competition. Rifampicin, the anti-TB drug is made through fermentation process. Ingredients of Cephalosporins are also made using fermentation process.

### ***Risks/Concerns***

#### **Very High Level of Debt**

Lupin has a very highly leveraged capital structure. Its debt was twice the equity at end FY02. We estimate debt at end FY03 to be around 1.6 times the equity. The high level of debt itself is not a cause of concern, given that interest coverage at around 3 is adequate enough. Moreover, it will have positive free cash flows to pay interest and repay debt.

What concerns us is that the high level of debt puts it at a weak negotiating position against potential licensees of NCEs. Potential licensees know that Lupin does not have financial sinews to undertake clinical trials.

There have been rumors innumerable number of times in the past that promoters will sell part of their stake (Promoters stake is 67.22%) and route the cash into the company to repay debt. The company has denied this every time. We are not clear how the promoters



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will route this cash into the company. This probably will happen by way of group companies repaying advances made to them. At end FY03, total debt was around Rs.6bn and equity was around Rs.3.8bn. Total loans & advances at end FY02 were over Rs.2.5bn. If and when it happens it will not only alleviate our above-mentioned concern, it will also be highly value-accretive.

### **Sales receivables are also very high**

Lupin had 113 days of sales outstanding at end FY02 (120 days at end FY01). The high level of receivables indicates weak bargaining position vis-à-vis customers, especially when the company had to fund it through large dose of debt. At end FY02, sales receivables at Rs.3.3bn were more than 50% of total debt Rs.6.5bn.

### **Regulatory and Litigation Risks**

These risks are common to all pharma companies.

### **Valuation**

This is a quick report and will be followed by a detailed report that will carry projections and valuation. Our ballpark estimates suggest that the stock is undervalued at current price and offers sizeable appreciation potential from here. It currently trades at 10 times trailing consolidated EPS (Rs.19.30).



## **Important Disclosure**

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