



**PHARMACEUTICALS EXPORT PROMOTION COUNCIL**  
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## **Indian pharmaceutical industry has tremendous potential to grow from the current levels**

*By Nirmal Bang*

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A highly organized sector, the Indian pharmaceutical industry is estimated to be worth \$4.5 billion, growing at about 8% to 9% every year.

The pharma industry in India ranks very high in Third World countries, in terms of technology, quality and range of medicines manufactured.

Globally the Indian pharmaceutical industry ranks fourth in terms of volume (with an 8% share in global sales), 13th in terms of value (with a share of 1% in global sales) and produces 20% to 24% of the world's generic drugs (in terms of value).

The Indian pharmaceutical sector is highly fragmented. It has more than 20,000 registered units and faces severe price competition along with government price control. The pharma industry has grown exponentially in the last two decades.

As many as 250 leading pharmaceutical companies control over 70% of the market, with the market leader holding nearly 7% of the market share.

India is emerging as the global hub for contract research and manufacturing services due to a combination of low-cost and world-class quality standards.

According to a study by Ernst & Young, the total market for clinical research activities in India is expected to touch \$1.5 billion - \$ 2 billion by 2010.

With pharma majors facing increased pressure on profit margins, spiraling R&D costs and rising overheads, outsourcing of clinical research processes to third parties in developing countries seems a viable option.

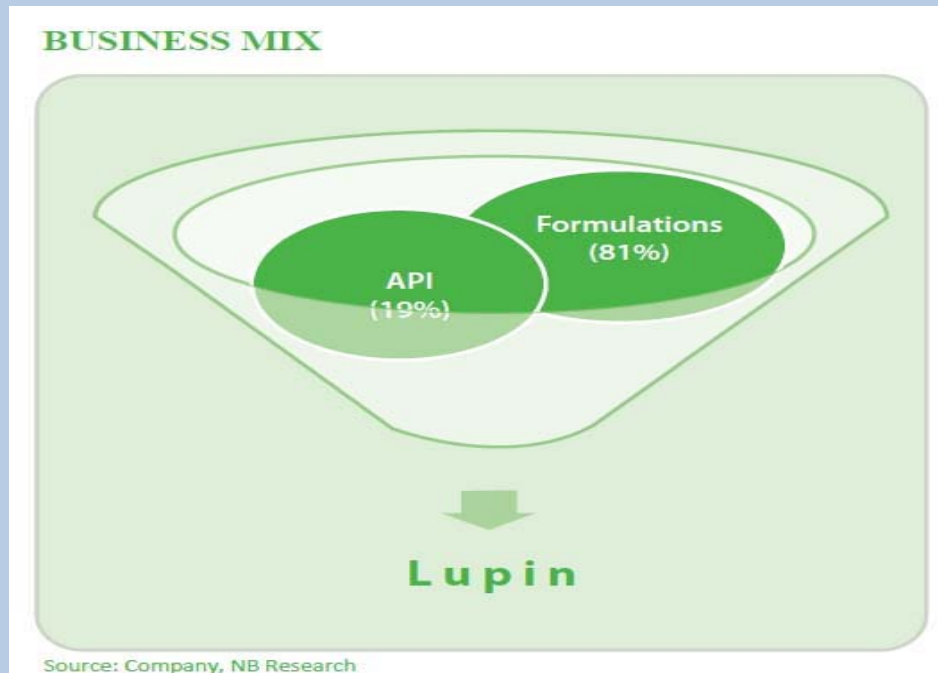
By contracting such work to India, they save 40% to 60% in new drug development. Consumer spending on healthcare went up from 4% of GDP in 1995 to 7% in 2007. That number is expected to rise to 13% of GDP by 2015.

### **LUPIN LTD**

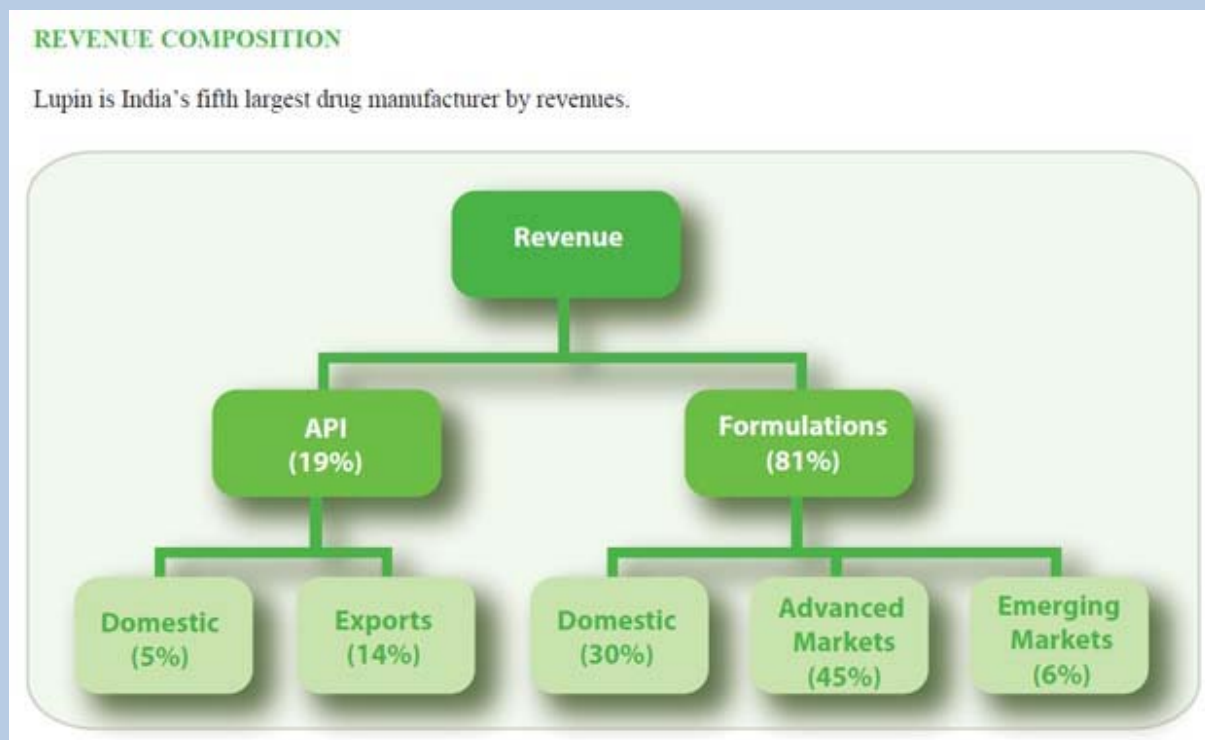
With over 40 years of history, Lupin is a big name in the Indian pharmaceutical industry. The Mumbai-

based firm has travelled a long way from being an API manufacturer to an innovation-led transnational company.

Promoted by Dr Desh Bandhu Gupta, Lupin went public in 1993-94. The company is the largest manufacturer of the tuberculosis drug in the world.



The company focuses on complex generics and branded formulations which gives it an upper edge over other generic players.



## DOMESTIC MARKETS

Lupin has been one of the fastest growing pharmaceutical companies, rising at over 23% CAGR for the past four years. It is among the top five companies of the IPM, with an overall market share of 2.73%.

The company is present across therapeutic segments like respiratory (number 2 with 11.9% market share), cardiac market (share 5.1%), diabetes, neuro psychiatry, oncology and anti-infective segments among others

The company recently added new therapy areas like gynecology and oncology to its portfolio.

### Top Ten Lupin Brands

Products	Therapeutic Segments	Segment Ranking
Tonact	CVS	2
Gluconorm	Anti-Diabetic	3
Rcinex	Anti-TB	1
Rablet	Gastro Intestinal	1
AKT	Anti-TB	2
Ramistar	CVS	2
Clopitab	CVS	1
L-Cin	Levofloxacin	1
Odoxil	Anti-Infective	1
Lupenox	CVS	2

Source: Company, NB Research

## EXPORTS

Export contributes around 65% to the company's consolidated revenues. Its major markets are

### United States

Lupin is the best player among Indian peers in the US.

- **Generics:** Backed by mainstay products and Intellectual Property (IP), the company has emerged as the fastest growing generics company in the US, by prescriptions, clocking over 90% y-o-y growth and is the ninth largest generics player in the US, in terms of total prescriptions. The company has a total of 22 products in the market. Eight of them are market leaders.

- **Branded:** Lupin's branded business contributes 27% to the overall US business. The company is aggressively seeking in-licensing opportunities and alliances to add new products to further augment the branded business.

### Europe

The company has a solid foundation with a product pipeline in anti-infective, cardiovascular and CNS therapy products. It intends to make around 15 EDMFs/COSs per year in European markets, currently 54 EDMFs/COSs

## Other Countries

It has a strong presence in Asia, Africa, Middle East, Latin America (AAMLA), Australia, etc. Lupin concentrates on chronic therapies and lifestyle segments like cardiovascular, central nervous system, gastro intestinal as well as anti-infectives, anti-asthma and anti-TB treatments. During FY08-09, these markets accounted for 15% of the company's consolidated revenues.

## Japan

Lupin has become the largest Indian player in Japanese markets post Kyowa acquisition. Kyowa is amongst the top 10 generic companies in Japan and has over 50 years of history in manufacturing and marketing pharmaceutical products. The company has identified neurology, cardiovascular, gastroenterology and respiratory as core therapeutic areas for drug development and marketing in Japan. Kyowa's FY09 sales contributed 12% of consolidated revenues.

## MANUFACTURING BASE

Lupin has 10 (6 formulations and 4 API) state-of-the-art manufacturing facilities, which adds to the company's overall ability to deliver quality products and ensures scalability of a wide range of product portfolio.

### Manufacturing Facilities

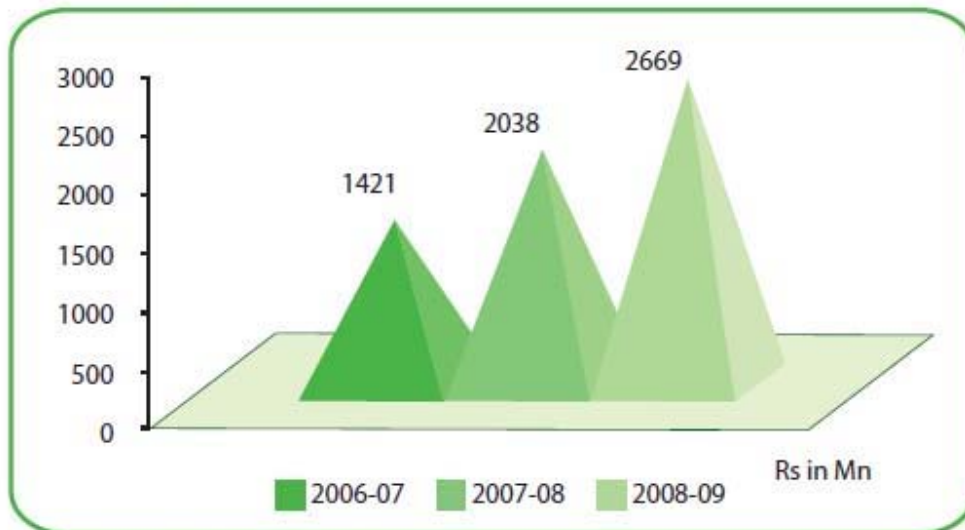
Location	Key Product	Approvals
Ankleshwar	API	WHO (Geneva)
Tarapur	API	US FDA, WHO
Mandideep	API	WHO, US FDA, UK MHRA
Mandideep	Formulations	WHO, US FDA, UK MHRA
Aurangabad	Formulations	WHO (Geneva)
Goa	Formulations	US FDA, UK MHRA
Vadodara	Contract Manufacturing	-
Jammu	Formulations	-
Indore	Formulations	In the pipeline
Sanda, Japan	Formulations	MOH (Japan)

Source: Company, NB Research

## RESEARCH & DEVELOPMENT

The Lupin Research Park (LRP) located at Pune is spread across 19 acres and is the hub of the company's research activities. The company's research programme covers the entire value chain, from developing complex APIs to value added, controlled release, first-to-files, to difficult-to-replicate products, to a highly evolved ADDS and NDDD programme.

## R&D Expenditure



Source: Company, NB Research

Housing a pool of over 550 scientists, the company spends over 7% of the consolidated net sales on R&D, which is among the highest in the industry.

Lupin's R&D activity is spread across

- Generic Research
- Process Research
- Formulations Research
- Advanced Drug Discovery Systems (ADDS)
- Novel Drug Discovery and Development (NDDD)
- Biotechnology Research

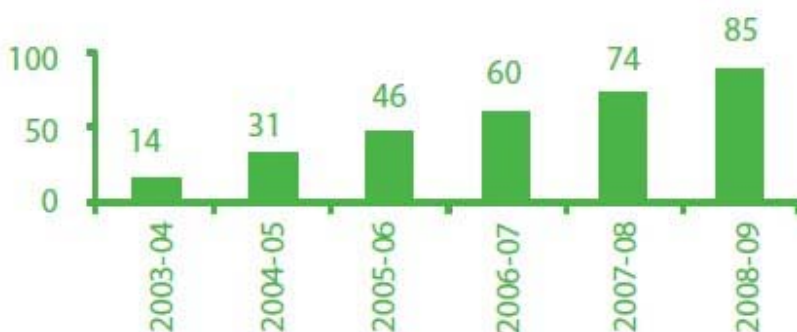
During FY08-09, the company filed a record 28 ANDAs, with as many as 5 first-to-files. Lupin's cumulative filings stand at 90, addressing an estimated market size of US\$ 90 billion.

## Cumulative ANDA Filings



Source: Company, NB Research

## Cumulative DMF Filings



Source: Company, NB Research

Lupin's Intellectual Property Management Group (IPMG) works in conjunction with the research and marketing team to identify lucrative opportunities.

The company's biotech activities have come a long way since they were initiated two years ago. Today, the company has 7 proteins in different stages of development. During FY08-09, Lupin set up a state-of-the-art biotech facility on the outskirts of Pune.

Lupin's NDDD program is an important pillar of the company's long-term growth plans. It has a pipeline of four Investigational New Drugs (IND) addressing three different disease areas of migraine, psoriasis and tuberculosis. These drug candidates are in the various phases of clinical development.

Another important aspect of scaling to newer orbits would be introducing new business lines and adding new therapy areas each year for the company. In FY08-09, the company entered the Oral Contraceptives (OC) segment through the filing of 7 OC ANDAs. Associated DMFs also instituted research in

Ophthalmological drugs.

The Indian Contract Research and Manufacturing Services (CRAMS) have been rapidly gaining momentum with its low-cost base and skilled manpower. Lupin initiated its CRAMS business through an acquisition, Novodigm, way back in 2007.

## **GROWTH DRIVERS**

### **Domestic**

Lupin is a market leader in anti-TB and CVS segments. The company is growing over 20% CAGR in domestic markets almost twice the industry average. It is expected to continue with this run rate in the future also. CRAMS: India is the flavour of the segment with its low cost base and skilled manpower. Global CRAMS market was estimated to be approximately US\$ 55 billion in 2007 and is expected to reach US\$ 64 billion by 2010 (excluding clinical trials market). It has entered the segment with the acquisition of Novodigm and is ramping up the business.

### **Exports**

**Niche products:** CVS, asthma, CNS among others would drive growth in the US as well as other markets as lifestyle segments have comparatively better margins. Pressure on cost containment is pushing generics sales, which is a positive for a pharmaceutical giant like Lupin Ltd. Also, significant patent expiry provides a window for growth in developed markets.

**Branded Formulations:** In the US, Lotrel would be the key growth driver for the company. Lupin recently got the approval for this product having a market size of US\$ 1.1 billion. This exemplifies that Lupin has strong research and development capabilities with strong execution skills.

New geographies like Japan are now opening up. Lupin has already made its presence felt in Japan, which is the second largest pharmaceutical market (worth over US\$ 65 billion), by acquiring Kyowa. Japan's stringent regulatory guidelines act as entry barriers for other companies thus limiting competition. Exports are expected to grow over 25% in future.

### **Inorganic**

Lupin has made some strategic acquisitions in the last two years, which enhanced the company's penetration in developed markets. Products like Antara, AllerNaze provide a strong foothold in the primary care markets.

### **NDDD**

The company has a strong NCE pipeline of 6 molecules including two molecules in phase II and one in phase III. Anything positive in the segment like an outlicensing deal would be a big catalyst for the company's growth.

## Financials

Particulars (Rs in Cr)	FY06	FY07	FY08	FY09	FY10 (9 months)
Gross Sales	1695	2014	2706	3776	3456
Other Op Income	67	174	185	91	81
<b>Net Sales</b>	<b>1762</b>	<b>2188</b>	<b>2892</b>	<b>3867</b>	<b>3537</b>
Cost Of Materials	826	932	1164	1604	1481
Personnel Exps	169	220	308	487	425
Manufacturing & Other Exps	477	569	799	1,036	945
<b>EBITDA</b>	<b>290</b>	<b>467</b>	<b>621</b>	<b>739</b>	<b>686</b>
Margins (%)	16.5	21.3	21.5	19.1	19.4
Depreciation	41	47	65	88	83
<b>PBIT</b>	<b>250</b>	<b>420</b>	<b>556</b>	<b>651</b>	<b>603</b>
Interest	31	37	37	50	31
Other Income	67	182	21	5	9
<b>PBT</b>	<b>286</b>	<b>564</b>	<b>540</b>	<b>606</b>	<b>581</b>
Tax	52	99	132	98	107
Tax Rate (%)	18.2	17.5	24.4	16.2	18.4
<b>PAT</b>	<b>234</b>	<b>466</b>	<b>408</b>	<b>508</b>	<b>475</b>
Minority Interest	0	0	0	3	14
EO Items	0	0	0	3	0
<b>PAT Reported</b>	<b>233</b>	<b>465</b>	<b>408</b>	<b>502</b>	<b>461</b>
Equity Capital (FV Rs 10)	82.82	82.82	82.82	82.82	82.82
<b>EPS</b>	<b>28.2</b>	<b>56.2</b>	<b>49.3</b>	<b>60.6</b>	<b>55.7</b>

Lupin remains an attractive long-term player considering the aging population in developed markets, demand for generics, its proven track record and its leadership position in various segments.

At the current market price of Rs 1572, the stock trades at 21x FY10 (nine months annualized earnings of Rs 74.3). Given the strong fundamentals and earnings momentum, the stock has potential to grow from its current levels.