

Lupin cranks up the R&D Engine

- Two IND applications filed with DCGI
- Six ANDAs and five DMFs filed during the quarter, totaling to eight ANDAs and seven DMFs for H1 2004-05
- R&D Expenditure for H1 2004-05 touches Rs. 355 million

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**Note – the figures in brackets indicate figures for the previous year*

Mumbai, 27 October 2004. In a substantial acceleration of its R&D programme, Lupin Limited has filed six Abbreviated New Drug Applications (ANDAs) and five Drug Master Files (DMFs) in the quarter ending 30 September 2004. This brings the total number of ANDAs filed during fiscal 2004-05 to eight. Lupin already has five ANDAs approved by the USFDA. The cumulative total of DMF filings is 21.

In addition to these filings with the USFDA, the company has also filed two Investigational New Drug Applications (INDAs) during the quarter with the Drug Controller General of India for new anti-TB and anti-Psoriasis molecules.

During the quarter the company has spent Rs. 183 million (Rs. 75 million) on R&D expenses taking the total R&D spend during H1 2004-05 to Rs. 355 million (Rs. 129 million).

“We are investing for the future,” Lupin Chairman Dr. Desh Bandhu Gupta said. “I believe that in the long term what will distinguish great pharma companies from good ones is the Intellectual Property they own. At Lupin we have taken a conscious decision to build this property and have decided to increase our spend on R&D from 3% of sales earlier to 8% of sales this year” he said.

Dr. Kamal Sharma, Managing Director said Lupin’s long-term growth strategy was to invest in building brands in the advanced markets. During the quarter the company spent Rs.73 million (Nil) towards sales promotion for Suprax® in the US market. “Suprax® has been off to a slower start than anticipated since the brand was out of the market for over a year. Recent approval of physician samples and progress with some managed care accounts will help in building the share. We expect steady progress in prescription development as the flu season develops. Already we have attained 14% of the Wyeth last share of the suspension prescriptions. We believe, we need to continue investing to build a significant presence in the market”, he said.

For the quarter ended 30 September 2004, the company reported gross sales (including excise duty) of Rs. 3307 million (Rs. 3609 million). Net sales for the quarter were at Rs. 3164 million (Rs. 3457 million). Sales in the corresponding quarter of the previous financial year had got a boost from the launch of Cefuroxime Axetil in the US market, which had contributed Rs. 324 million. Excluding this, net sales showed a growth of 1%.

Interest and finance charges for the quarter were lower at Rs. 62 million (Rs. 150 million). Provision for Tax (including deferred tax) was lower at Rs. 18 million (Rs. 123 million) as a result of increased R&D spend and sales from the prils facility at Mandideep, which has EOU certification. Net profit for the quarter was at Rs. 175 million, as against Rs. 9 million a year ago, after an extraordinary charge of Rs. 509 million.

Advanced market revenues were at Rs. 526 million (representing 17% of the total net sales) as against Rs. 854 million in the previous year, which included revenue of Rs. 324 million from Cefuroxime Axetil, launched in the US.

For the half-year ended 30 September 2004, Lupin reported a 1% growth in net sales at Rs 6154 million (Rs. 6094 million). This was on account of lower sales of finished products to advanced markets and lower price realisations of Pen G based APIs. Net profit was at Rs. 381 million, as against Rs. 289 million a year ago, after an extraordinary charge of Rs. 509 million.

HIGHLIGHTS

Finished products to developing markets

- Finished products revenues from developing markets (including India) increased by 8% at Rs. 1563 million (Rs. 1449 million).
- Finished product revenues from India increased by 11% to Rs. 1479 million (Rs. 1333 million).
- Exports to developing markets were at Rs. 84 million (Rs. 117 million).
- Lupin's growth as per ORG-IMS for July-September 2004 was at 13%, close to three times the average industry growth.
- Nine products launched in the domestic market in varied therapeutic segments.
- Anti- asthma range of products launched in the domestic market, leveraging equity with chest physicians.

H1 FY05 revenues from finished products to developing markets (including India) grew by 23% to Rs. 3040 million (Rs. 2476 million).

APIs to developing markets

- API revenues from developing markets (including India) were at Rs. 1051 million (Rs. 1133 million).
- Export revenues were lower by 10% at Rs. 691 million (Rs. 769 million). This was primarily on account of lower selling prices of Pen G based cephalosporins.
- Domestic market revenues were at Rs. 360 million (Rs. 364 million).

H1 revenues from APIs to developing markets (including India) were at Rs. 2155 million (Rs. 2344 million). Of this exports revenues were at Rs. 1461 million (Rs. 1643 million) and domestic revenues were at Rs. 694 million (Rs. 701 million).

APIs and finished products to advanced markets

- Revenues from the advanced markets were at Rs. 526 million (Rs. 854 million).
- Export of APIs (active pharmaceutical ingredients) to the advanced markets were at Rs. 514 million (Rs. 530 million)
- Increase in Lisinopril sales to advanced market was in line with the expected increase in customer base, which resulted in advanced market revenues from APIs increasing by 81% on a sequential basis.
- Suprax® prescriptions has seen an increasing trend on a month on month basis.
- Injectibles facility at Mandideep receives TGA (Australia) approval

Research and Development

- Six ANDAs filed in the quarter. Cumulative ANDA filings at 13, of which eight are pending approval.
- Five DMFs filed in the quarter. Cumulative DMF filings at 21.
- IND application filed with the DCGI for anti-TB and anti-psoriasis molecules
- 17 patents filed in the current fiscal, taking the cumulative filings to 162, of which 55 have been granted (including 21 in US and EU)