

Lupin Limited

Instruments	Amounts	Rating Action
	(Rs. Crore)	
Non-convertible debenture programme	100.00	[ICRA]AAA (Stable) reaffirmed
Long-term, fund-based facilities	150.00	[ICRA]AAA (Stable) reaffirmed
Long-term, non-fund based facilities	40.00	[ICRA]AAA (Stable) reaffirmed
Short-term, fund-based facilities	950.00	[ICRA]A1+ reaffirmed
Short-term, non-fund based facilities	360.00	[ICRA]A1+ reaffirmed

ICRA has reaffirmed the [ICRA]AAA (pronounced ICRA triple A) rating assigned to the Rs. 100.0 crore¹, non-convertible debenture programme; the Rs. 150.0 crore, long-term, fund-based facilities and the Rs. 40.0 crore, long-term, non-fund based facilities of Lupin Limited (Lupin)². ICRA has also reaffirmed the [ICRA]A1+ (pronounced ICRA A one plus) rating assigned to the Rs. 950.0 crore, short-term, fund-based facilities and the Rs. 360.0 crore, short-term, non-fund based facilities of Lupin. The outlook on the long-term rating is 'Stable'.

The reaffirmation of ratings takes into consideration Lupin's strong and well-diversified business model supported by branded formulations business (in India and US), generics business (with leadership position in certain therapeutic segments) and backward integration through presence in APIs. ICRA notes the steep increase in borrowing levels of the company as on March 31, 2016 owing to the debt-funded acquisition of GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. (GAVIS, renamed as Lupin-Somerset) and the high working capital requirements following the launch of the generic version of Glumetza® in Q4 FY2016. Nonetheless, the credit profile of the company remains strong as characterized by comfortable capital structure and robust cash accruals from existing established business and inflows from the recent acquisitions, particularly GAVIS.

The US generics market – the largest contributor to Lupin's revenues has been supported by 21 new product launches in FY2016, key among them being the First-to-File (FTF) generic version of Glumetza® (launched in February 2016) and the generic version of Exforge® (launched in April 2015), besides a few oral contraceptives (OCs), including the generic version of Ortho Tri-Cyclen® (launched in January 2016). However, the generics business in the US has been impacted by price erosion owing to the ongoing channel consolidation, leading to a slowdown in the y-o-y growth rate to 9% in FY2016.

As on March 31, 2016, Lupin has 124 commercialised products in the US market, including Lupin – Somerset's 28 products. The company has filed a total of 343 Abbreviated New Drug Applications (ANDAs), including 102 from the Lupin – Somerset facility. Of these, 180 products are approved (including 44 from the Lupin – Somerset facility). The 163 aggregate pending ANDAs address a market size of USD 63.8 billion, with 45 FTFs (addressing a market size of USD 11.9 billion) and 25 exclusive FTFs (addressing a market size of USD 4.4 billion). Further, the acquisition of GAVIS is expected to aid Lupin in scaling up its US generics business and broaden its product pipeline through access to controlled substances and other niche, high-value complex generics and speciality products. As on March 31, 2016, oral solids/ liquids constitute ~63% of the 163 products pending approval, while dermatological and controlled substances constitute ~16% and ~8%, respectively.

In the US branded formulations segment, the un-arrested decline in revenues in FY2016 is attributable to the genericisation of 'Suprax' since April 2015 and the soft flu season in the fiscal, combined with the impact of increasing generic competition for 'Antara' post launch of Tricor generics. Meanwhile, the recently launched InspiraChamber® (under a strategic licensing agreement with the New Jersey-based respiratory research and development company InspiRX) has garnered a market share of 3.7% in the US, thus giving competition to the AeroChamber product of Forrest Labs, which was previously promoted by Lupin (the deal expired in Q1 FY2014). Also, the acquisition of the US-based GAVIS has given Lupin access to certain products like Methergine®, which was launched as a branded product during April 2016, though initially not targeted at the

¹ 100 Lakh = 1 Crore = 10 Million

² For complete rating scale and definitions, please refer to ICRA's website www.icra.in or other ICRA Rating Publications



branded market by GAVIS. The Lupin – Somerset portfolio also includes Methylphenidate, which may also be launched as a branded product in the US market.

During FY2016, Lupin has received five Form 483s from the US Food and Drug Administration (USFDA) for various manufacturing facilities. While none of the observations are deemed serious and have not impacted production at the respective facilities, their timely resolution and prevention of further violations is crucial. Till date, the company has received Establishment Inspection Report (EIR) for all the above mentioned facilities, except for the Goa facility which received Form 483 during March 2016.

The domestic formulations business – which is the second largest contributor to Lupin’s revenues – was supported by 19 new brand launches in FY2016. Lupin has been consistently growing ahead of the Indian pharmaceutical market growth, driven predominantly by the chronic therapies, which constitute ~87% of Lupin’s domestic formulations portfolio. However, the pace of growth in FY2016 has slowed to 14% y-o-y, due to the increased number of the company’s products (currently ~24% of the domestic portfolio) being brought under the purview of the National List of Essential Medicines (NLEM) and the proposed Fixed Dose Combination (FDC) drugs. Nonetheless, the company is expected to continue to outperform the industry growth.

Apart from the US and domestic markets, Lupin has strong business positions in other key markets like Japan, Europe, Russia, South Africa, Mexico and Brazil and continues to expand its footprint through acquisitions as reflected by its acquisition of Medquimica Industria Farmaceutica S.A in May 2015 in Brazil (which complements the business of previously acquired Laboratories Grin S.A. De C.V. in Mexico), ZAO Biocom in July 2015 in Russia (the integration of which is ongoing) and the acquisition of the speciality portfolio of Temmler Pharma GmbH & Co. KG in Germany in July 2015.

Aided by a well-diversified business model, strong product launches with increasing share of complex or limited competition products, backward integration through presence in APIs together with prudent capital management, Lupin’s financial profile is marked by robust profitability and credit metrics. The operating margin, however, declined to 27.3% in FY2016 from 29.9% in FY2015, owing to the increased research and development (R&D) expenses (11.7% of net sales in FY2016 as compared to 8.7% in FY2015).

Company Profile

Lupin (erstwhile Lupin Chemicals) was founded in 1968 by Dr. Desh Bandhu Gupta, the current Chairman, when he bought over the Lupin trade mark from a company called Charak Pharmaceuticals. Set up originally as a proprietary concern, it was converted into a private limited company in 1972, and became a public limited company in 1992. In June 2001, Lupin Chemicals Limited merged with Lupin Laboratories Limited, following which the name of the merged entity was changed to Lupin Limited. The amalgamation was aimed at leveraging the strengths of the two companies. Lupin is an integrated pharmaceutical company with presence across research, manufacturing and marketing of formulations and APIs. The company’s business mix can be broadly divided into two segments – formulations (accounted for 91% of Lupin’s revenues in FY2016) and APIs (9%). Lupin has a well-diversified geographic presence with sales to the advanced markets (US, Europe and Japan) accounting for nearly 56% of the company’s total formulations sales (in FY2016). In addition to being amongst the top five generic players (in terms of prescriptions) in the US market, Lupin is also amongst the few Indian pharmaceutical companies to have a presence in the high potential branded formulations market in the US, though this segment is currently de-growing. Lupin continues to remain an established player in the domestic formulations market, where it has diversified its presence across therapeutic segments, with fast-growing lifestyle related segments contributing 69% to its domestic formulations sales in FY2016.

Recent Results

For the twelve months ended March 31, 2016, Lupin (consolidated) reported a profit after tax (PAT) of Rs. 2,258.8 crore on an operating income of Rs. 14,165.7 crore as against a PAT of Rs. 2,442.4 crore on an operating income of Rs. 12,735.6 crore for the twelve months ended March 31, 2015.

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For further details, please contact:

Analyst Contacts:

Mr. Subrata Ray (Tel. No. +91 22 6114 3408)
subrata@icraindia.com

Relationship Contacts:

Mr. L. Shivakumar, (Tel. No. +91 22 6114 3406)
shivakumar@icraindia.com

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**Registered Office****ICRA Limited**

1105, Kailash Building, 11th Floor, 26, Kasturba Gandhi Marg, New Delhi 110001
Tel: +91-11-23357940-50, Fax: +91-11-23357014

Corporate Office**Mr. Vivek Mathur**

Mobile: +91 9871221122

Email: vivek@icraindia.com

Building No. 8, 2nd Floor, Tower A, DLF Cyber City, Phase II, Gurgaon 122002
Ph: +91-124-4545310 (D), 4545300 / 4545800 (B) Fax; +91- 124-4050424

Mumbai**Mr. L. Shivakumar**

Mobile: +91 9821086490

Email: shivakumar@icraindia.com

3rd Floor, Electric Mansion
Appasaheb Marathe Marg, Prabhadevi
Mumbai—400025,
Board : +91-22-61796300; Fax: +91-22-24331390

Kolkata**Mr. Jayanta Roy**

Mobile: +91 9903394664

Email: jayanta@icraindia.com

A-10 & 11, 3rd Floor, FMC Fortuna
234/3A, A.J.C. Bose Road
Kolkata—700020
Tel +91-33-22876617/8839 22800008/22831411,
Fax +91-33-22870728

Chennai**Mr. Jayanta Chatterjee**

Mobile: +91 9845022459

Email: jayantac@icraindia.com

5th Floor, Karumuttu Centre
634 Anna Salai, Nandanam
Chennai—600035
Tel: +91-44-45964300; Fax: +91-44 24343663

Bangalore**Bangalore****Mr. Jayanta Chatterjee**

Mobile: +91 9845022459

Email: jayantac@icraindia.com

'The Millenia'
Tower B, Unit No. 1004, 10th Floor, Level 2 12-14, 1 & 2,
Murphy Road, Bangalore 560 008
Tel: +91-80-43326400; Fax: +91-80-43326409

Ahmedabad**Mr. L. Shivakumar**

Mobile: +91 9821086490

Email: shivakumar@icraindia.com

907 & 908 Sakar -II, Ellisbridge,
Ahmedabad- 380006
Tel: +91-79-26585049, 26585494, 26584924; Fax:
+91-79-25569231

Pune**Mr. L. Shivakumar**

Mobile: +91 9821086490

Email: shivakumar@icraindia.com

5A, 5th Floor, Symphony, S.No. 210, CTS 3202, Range
Hills Road, Shivajinagar, Pune-411 020
Tel: + 91-20-25561194-25560196; Fax: +91-20-
25561231

Hyderabad**Mr. Jayanta Chatterjee**

Mobile: +91 9845022459

Email: jayantac@icraindia.com

4th Floor, Shobhan, 6-3-927/A&B. Somajiguda, Raj
Bhavan Road, Hyderabad—500083
Tel:- +91-40-40676500