November 10, 2017

Lupin Limited

Summary of rated instruments

Instrument*	Amount Rated (in Rs. crore)	Rating Action
Non-Convertible Debenture Programme	100.0	[ICRA]AAA (on rating watch with developing implications); Re-affirmed
Long-term, Fund-based Facilities	150.0	[ICRA]AAA (on rating watch with developing implications); Re-affirmed
Long-term, Non-fund Based Facilities	40.0	[ICRA]AAA (on rating watch with developing implications); Re-affirmed
Short-term, Fund-based Facilities	950.0	[ICRA]A1+ (on rating watch with developing implications); Re-affirmed
Short-term, Non-fund Based Facilities	360.0	[ICRA]A1+ (on rating watch with developing implications); Re-affirmed

*Instrument details are provided in Annexure-1

Rating action

ICRA has re-affirmed the long-term rating of [ICRA]AAA (pronounced ICRA triple A)[1] assigned to the Rs. 100.0 crore[2] 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). ICRA has also re-affirmed the short-term rating of [ICRA]A1+ (pronounced ICRA A one plus) 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 ratings continue to be on 'rating watch with developing implications'.

Rationale

The continuation of rating watch with developing implications follows the issue of warning letters by the United Food and Drug Administration (USFDA) to the Goa and Indore (Pithampur Unit II) formulations manufacturing facilities of Lupin in November 2017. ICRA notes that this action by USFDA may delay the product approvals from these facilities, which contribute more than 60% of Lupin's US supplies, thus impacting the revenue growth and profitability. The timely resolution of the warning letters at both the facilities is critical, and remains a key rating sensitivity.

ICRA ratings takes into account Lupin's strong and well-diversified business model supported by the branded formulations business (in India and the US), generic business (with leadership position in certain therapeutic segments) and backward integration through presence in active pharmaceutical ingredients (APIs).

Based on the company's public commentary post acquisition, and ICRA's discussion with the management, ICRA takes comfort from the revenue and profits potential from the launch of the lead investigational drug Solosec™ (secnidazole oral granules). It was acquired from Symbiomix Therapeutics LLC in the US, despite the significant initial investments required towards ramp up of supplies and marketing expenses associated with the launch of the product.

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

[2] *100 lakh = 1 crore = 10 million*

Aided by product launches with increasing share of complex or limited competition products together with prudent capital management with respect to new investments, Lupin's financial profile is marked by healthy operating profit margins (though moderated in H1 FY2018), strong cash flow generation and comfortable debt protection metrics. ICRA notes that the price erosions from increased competition on Lupin's key products such as Glumetza and Fortamet, and channel consolidation in the US, along with delayed product launches following regulatory issues at its formulations manufacturing facilities at Goa and Pithampur (Madhya Pradesh) have impacted the revenue growth and profits in H1 FY2018. The company has reported YoY de-growth of ~10% in revenues and a decline in operating profit margin to 21.8% in H1 FY2018 from 27.2% in FY2017.

Lupin is expected to continue to pursue its acquisition strategy to augment its existing branded drugs portfolio, expand its geographical presence in other markets, further strengthen its presence in the Japanese market, as well as research and development (R&D) through its acquisition of technology-based companies. However, ICRA expects Lupin's credit profile and liquidity position to remain healthy, supported by a strong pipeline of products yet to be commercialised across all its key markets. Large inorganic investments by the company would remain an event risk, and the impact of such investments on the company's business and credit profile would be monitored on a case by case basis.

Key rating drivers

Credit strengths

- **Strong and well-diversified business model supported by branded formulations business (in India and regulated markets), generics business (with leadership position in certain segments) and backward integration into APIs –** The revenue profile of Lupin is diversified, across both branded and generic formulations in regulated and non-regulated markets. Markets in the US, Europe and Japan together contributed ~53% to total consolidated sales in H1 FY2018 (~60% in FY2017). US branded sales contributed ~9% to total US formulations sales in H1 FY2018 (~6% in FY2017). Lupin's API manufacturing capabilities are predominantly focussed on its captive requirements for formulations–~90% of APIs manufactured is consumed in-house. Sales from APIs contributed ~7% to total consolidated revenues in FY2017 and H1 FY2018.
- **Robust abbreviated new drug applications (ANDA) filings, steady product launches, vertical integration and established relationships with channel partners have allowed Lupin to emerge as the fourth largest generic company in the US by prescriptions; strong market positions in several other geographies –** Following the acquisition of Gavis Pharmaceuticals LLC (now Lupin Somerset) in July 2015, Lupin has the fifth largest pipeline of ANDA products, with 377 ANDA filings as on September 30, 2017. Of these, 225 have been approved and 147 products (including nine products launched in H1 FY2018) have been commercialised, indicating a large part of the product pipeline is yet to come into play. In terms of market position, Lupin is the fourth largest generics player (in terms of prescriptions) in the US market. The company has a meaningful presence in India (sixth largest as per IMS March 2017 in emerging markets), Japan (sixth largest generic player in advanced markets as per IMS March 2017) and other markets like South Africa (fourth largest in emerging markets), Philippines and Australia.
- **Strong pipeline of limited-competition, difficult-to-manufacture products for the US generic market to support future growth and profitability –** Lupin's presence in the US generics business is marked by a product basket comprising niche, complex molecules in therapeutic areas of cardiovascular systems (CVS), central nervous system (CNS), oral contraceptives (OCs), dermatology, respiratory and ophthalmology, among others. The limited competition products expected to be launched in the near term include Ranleva, Ranexa, Levothryoxine, Tamiflu, Advair, and Lialda, among others. However, these are contingent on the timely resolution of the warning letter issued to its manufacturing facilities at Goa and Pithampur Unit II.

- **Lupin's domestic formulations business has continuously outperformed the Indian pharmaceutical market growth –** Lupin reported ~12% YoY growth in FY2017 in the domestic formulations business as against the Indian pharmaceutical industry growth of 10.3%[3], supported by new product launches and higher presence in the chronic segment. However, it reported a moderate growth of 7.5% YoY in H1 FY2018 due to the impact of de-stocking by the trade in Q1 FY2018, prior to the implementation of the goods and services tax (GST). This was still higher than the Indian pharmaceutical industry growth rate of 5.6%[4].
- **Among the few domestic pharmaceutical companies to have established a successful presence, although currently under stress, in the high-margin branded formulations market in the US**
- **Global leadership in several API segments, namely cephalosporin and CVS drugs -** Lupin has remained a global leader in cephalosporins (third generation anti-biotics), anti-tuberculosis (anti-TB) and the CVS space for over 15 years. It continues to gain traction with its global institutional business and remains among the largest suppliers of anti-TB products to the World Health Organisation's (WHO) global drug facility. Lupin is the only company pre-qualified by the WHO globally for both its anti-TB APIs and formulations.
- **Strong financial profile characterised by robust profitability and credit metrics -** While the big-ticket debt-funded acquisition of Gavis in March 2016 negated the erstwhile debt-free status of the company, the leveraging continues to remain comfortable as depicted by gearing (net debt/tangible networth) of 0.38 time as on September 30, 2017 supported by the robust accretion to reserves. The coverage indicators remain strong, as evinced by the NCA/ Net Debt of 60%, interest coverage of 16.77 times and Net Debt/OPBDITA of 1.09 times in FY2017. The operating profit margin remained healthy at 21.8% in H1 FY2018, although moderated from 27.8% in H1 FY2016 following the pricing pressures in the US business. Consequently, the debt metrics have also moderated as evinced by NCA/Net Debt of 51% and Net Debt/OPBITDA of 1.5 times in H1 FY2017.

Credit weaknesses

- **Channel consolidation in the US has resulted in reduction in profit margins across product segments -** During H1 FY2018, the company reported YoY de-growth of ~10% in revenues. This was mainly due to intense pricing pressure on base US generic business owing to higher competitive intensity (faster ANDA approvals by the USFDA), and consolidation in the supply chain leading to lower bargaining power. The other factor was the impact of GST on the domestic formulations business. The pricing pressure further led to a decline in operating profit margin to 21.8% during H1 FY2018, as against 27.2% in FY2017.
- **Warning letters issued to the Goa and Pithanpur Unit II formulations facilities; this may aggravate supply issues, if speedy resolution is not achieved –** The Goa formulations manufacturing facility has been issued a warning letter by the USFDA in November 2017. The Goa facility is vital for the company as it contributes a sizeable proportion of its US supplies and ANDA filings pending approvals. Furthermore, the company had also received a warning letter for its Pithampur unit II formulations manufacturing facility during November 2017. These will continue to delay product approvals and thus launches, further impacting the US formulations business in terms of both revenues and profits. ICRA thus expects the US formulations business to witness double digit de-growth in FY2018. The launch of the limited competition products from FY2019 onwards is contingent on the timely resolution of the warning letters.
- **Regulatory risks in developed markets, related to patent challenges, product launches and manufacturing facilities / processes**
- **Likelihood of further in-organic investments towards expanding geographic presence and strengthening portfolio of branded drugs –** Lupin is expected to continue to pursue its acquisition

[3] *MAT, March 2017*

[4] *MAT September 2017*

strategy to augment its existing branded drugs portfolio, expand its geographical presence in other markets, further strengthen its presence in the Japanese market and its R&D through the acquisition of technology-based companies. However, its steady cash flow generation and currently strong credit profile partly mitigate the risks.

- **R&D investments in novel drug delivery systems (NDDS) yet to realise any substantial returns; however, NCE development has shown progress -** The total R&D spend of the company in H1 FY2018 and FY2017 was Rs. 974 crore (12.3% of sales) and Rs. 2,310 crore (13.5% of sales), respectively. As the company climbs the complexity curve (complex generics, biosimilars and NDDS) and increases the number of filings, the level of R&D expenditure is expected to remain high. Nearly a sixth of the expected R&D spend would be targeted at NCE development, while another seventh or eighth would be aimed at biosimilars.

Analytical approach: For arriving at the ratings, ICRA has applied its rating methodologies as indicated below.

Links to applicable criteria:
Corporate Credit Rating - A Note on Methodology
Methodology for Pharmaceutical Industry

About the company:
Lupin Limited (erstwhile Lupin Chemicals) was founded in 1968 by the Late Dr. Desh Bandhu Gupta, the father of the current managing director, Mr. Nilesh Gupta, when Dr. Gupta had bought over the Lupin trade mark from Charak Pharmaceuticals in 1968. 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 merged with Lupin Laboratories Limited, following which the merged entity was renamed as Lupin Limited. The amalgamation was aimed at leveraging the strengths of the two companies. Lupin is an integrated pharmaceutical company with a presence across research, manufacturing and marketing of formulations and APIs.

Globally, Lupin is the seventh and the sixth largest generics pharmaceutical company by market capitalisation (June 30, 2017, Bloomberg) and revenues (March 31, 2017, Bloomberg), respectively. The company is the fourth largest pharmaceutical player in the US by prescriptions (Quintiles IMS MAT March 2017); second largest Indian pharmaceutical company by global revenues (March 31, 2017, Bloomberg); sixth largest generic pharmaceutical player in Japan and sixth largest company in Indian pharmaceutical market (Quintiles IMS MAT June 2017).

The company’s business mix can be broadly divided into two segments—formulations (accounted for 93% of Lupin’s consolidated revenues in FY2017) and APIs (accounted for 7% of Lupin’s consolidated revenues in FY2017). Lupin has a well-diversified geographic presence, with sales to advanced markets (the US, Europe and Japan) accounting for nearly 61% of the company’s total formulations sales in FY2017.

For the 12 months that ended March 31, 2017, Lupin (consolidated) reported a profit after tax (PAT) of Rs. 2,564.6 crore on an operating income (OI) of Rs. 17,375.6 crore, as against a PAT of Rs. 2,269.5 crore on an OI of Rs. 14,136.5 crore for the 12 months that ended March 31, 2016.

For the six months that ended September 30, 2017, Lupin reported a PAT of Rs. 813.7 crore[5] on an OI of Rs. 7,908.4 crore.

[5] *Before minority interest*

Key Financial Indicators (Audited)

	FY2016	FY2017
Operating Income (Rs. crore)	14,136.5	17,375.6
PAT (Rs. crore)*	2,269.5	2,564.6
OPBDIT/ OI (%)	27.1%	27.2%
RoCE (%)	29.3%	22.4%
Total Debt/ TNW (times)	0.6	0.6
Total Debt/ OPBDIT (times)	1.9	1.7
Interest Coverage (times)	20.3	16.8
NWC/ OI (%)	40%	30%

**before minority interest*

OI: Operating Income; PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation; ROCE: PBIT/Avg. (Total Debt + Tangible Net-Worth + Deferred Tax Liability - Capital Work - in Progress); NWC: Net Working Capital

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

Rating history for last three years:

Table:

S. No.	Instrument	Current Rating (FY2018)				Chronology of Rating History for the past 3 years			
		Type	Amount Rated (Rs. crore)	Date & Rating		Date & Rating in FY2017	Date & Rating in FY2016		Date & Rating in FY2015
				November 2017	October 2017	August 2016	July 2015	April 2015	-
1	Fund-based Facilities	Long-term	150.0	[ICRA]AAA (on rating watch with developing implications)	[ICRA]AAA (on rating watch with developing implications)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	-
2	Fund-based Facilities	Short -term	950.0	[ICRA]A1+ (on rating watch with developing implications)	[ICRA]A1+ (on rating watch with developing implications)	[ICRA] A1+	[ICRA] A1+	[ICRA] A1+	-
3	Non-fund based Facilities	Long-term	40.0	[ICRA]AAA (on rating watch with developing implications)	[ICRA]AAA (on rating watch with developing implications)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	-
4	Non-fund based Facilities	Short -term	360.0	[ICRA]A1+ (on rating watch with developing implications)	[ICRA]A1+ (on rating watch with developing implications)	[ICRA] A1+	[ICRA] A1+	[ICRA] A1+	-
5	Non-Convertible Debenture Programme	Long-term	100.0	[ICRA]AAA (on rating watch with developing implications)	[ICRA]AAA (on rating watch with developing implications)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	[ICRA] AAA (Stable)	-

Complexity level of the rated instrument:

ICRA has classified various instruments based on their complexity as "Simple", "Complex" and "Highly Complex". The classification of instruments according to their complexity levels is available on the website www.icra.in

Annexure-1
Instrument Details

ISIN No.	Instrument	Date of Issuance / Sanction	Coupon Rate	Maturity	Amount Rated (Rs. crore)	Current Rating and Outlook
-	Fund-based Facilities	-	-	Repayable on demand	150.0	[ICRA]AAA (on rating watch with developing implications)
-	Fund-based Facilities	-	-	Repayable on demand	950.0	[ICRA]A1+(on rating watch with developing implications)
-	Non-fund Based Facilities	-	-	Repayable on demand	40.0	[ICRA]AAA (on rating watch with developing implications)
-	Non-fund Based Facilities	-	-	Repayable on demand	360.0	[ICRA]A1+(on rating watch with developing implications)
-	Non-convertible Debenture Programme	Yet to be placed			100.0	[ICRA]AAA (on rating watch with developing implications)

Source: Lupin Limited

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About ICRA Limited:

ICRA Limited was set up in 1991 by leading financial/investment institutions, commercial banks and financial services companies as an independent and professional investment Information and Credit Rating Agency.

Today, ICRA and its subsidiaries together form the ICRA Group of Companies (Group ICRA). ICRA is a Public Limited Company, with its shares listed on the Bombay Stock Exchange and the National Stock Exchange. The international Credit Rating Agency Moody's Investors Service is ICRA's largest shareholder.

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