

November 10, 2021

Lupin Limited: Ratings reaffirmed; rated amount enhanced

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Short-term Fund-based Limits	1,100.0	-	-
Short-term Non-fund Based Limits	400.0	-	-
Short-term – Fund-based/ Non-fund Based Limits	-	2,678	[ICRA]A1+; reaffirmed
Total	1,500.00	2,678.0	

*Instrument details are provided in Annexure-1

Rationale

The rating continues to positively factor in Lupin Limited's (Lupin) strong business profile, geographically diversified revenue mix, with an established position in the key US and Indian pharmaceutical markets and its strong liquidity position. Lupin has a well-established presence in the US generics market and ranks third¹ in terms of generic sales in the US. It is the fifth² largest player in the domestic formulations segment. Lupin's near-term revenue outlook is healthy, with expected ramp-up of Albuterol (inhalation) and recently launched Arformoterol (inhalation, gBrovana) as well as pick-up in revenues from domestic markets. The company also has a robust pipeline of limited competition products (including inhalation products, injectables and biosimilars), which are expected to provide a fillip to its revenues in the medium term. As on September 30, 2021, Lupin had 152 ANDAs³ pending approval, including 51 first-to-files (FTFs).

ICRA notes that the company's financial performance remained subdued in FY2021 and H1 FY2022, due to its muted performance in its key market, the US. This was due to increased competitive pressures on its base portfolio, failure to supply penalties levied in Q1 FY2022, slow but improving ramp up of Albuterol and mid-high single digit pricing pressure for the US generic portfolio. However, the same was partly offset by launch and healthy offtake of Arformoterol and better traction in few base products in Q2 FY2022. Performance of Lupin's key speciality product, Solosec, was severely impacted during the pandemic. Consequently, the company undertook an impairment of Rs. 707.7 crore in Q2 FY2022 in light of the adverse changes in available market opportunity.

The domestic region continued to outperform the Indian pharmaceutical market (IPM) with respect to chronic and acute therapies, led by new product launches and higher offtake for acute and Covid related therapies in H1 FY2022. The OPM margins, excluding milestone income received in Q1 FY2022, declined in H1 FY2022 because of lower gross margins, one-time restructuring costs, increased overheads and research and development (R&D) expenses. The gross margins declined in H1 FY2022 because of inventory provisions, sales mix skewed towards acute therapies, rising raw material costs and pricing pressures. Furthermore, Lupin's net margins and return on capital employed was impacted in H1 FY2022 by the impairment expenses related to Solosec and sizeable provision made towards litigation settlement of Glumetza (Rs. 1,879.6 crore in Q2 FY2022, to be paid by Q3 FY2022). Despite this, Lupin's credit profile remains adequately supported by a strong liquidity position underpinned by sizeable cash and bank balances, liquid investments and unutilised working capital limits.

¹ Source: IQVIA MAT, September 2021, company presentation

² Source: IQVIA MAT, September 2021, company presentation

³ Abbreviated new drug applications

Lupin's ability to maintain a healthy product portfolio in the US market, while launching its complex generic and limited competition products are critical for its revenue growth and profitability. The rating factors in the pending resolution of four warning letters and one official action indicated (OAI) status issued to five of Lupin's plants. The rating also factors in the pending resolution of the ongoing industry-wide investigation by the anti-trust division of the US DoJ⁴ for price-fixing and price collusion allegations as well as other litigations. Lupin's profitability remains vulnerable to foreign exchange fluctuations because of its foreign operations and foreign currency borrowings, though it hedges them through forward contracts. Large inorganic investments by the company would remain an event risk, and the impact of such investments on its business and credit profile would be monitored on a case-by-case basis.

Key rating drivers and their description

Credit strengths

Strong and well-diversified business model – Lupin's revenue profile is diversified across regulated as well as non-regulated markets, with the US accounting for 33.5% of its total sales in H1 FY2022. It has a well-established presence in the US generics market and ranks third in terms of generic sales in the country. It is the fifth largest player in the domestic formulations segment, which contributed 38.6% to its total sales in H1 FY2022. Lupin's API⁵ manufacturing capabilities are predominantly focussed on its captive requirements for formulations with ~90% of its APIs being consumed in-house. Sales from APIs contributed ~6.2% to its total consolidated revenues in H1 FY2022.

Strong pipeline of limited competition products for US generics market to support future growth and profitability – Lupin has a robust pipeline of limited competition products (including complex generics, inhalation products, injectables and biosimilars), which are expected to provide a boost to its revenues in the medium term. As on September 30, 2021, Lupin had 152 ANDAs pending approval including 50 FTFs, of which 20 are exclusive opportunities. Recently, in June 2021, the company launched the authorised generic for Brovana (Arformoterol, inhalation) which is expected to contribute significantly to revenue and margin growth in FY2022. The company has other respiratory products, complex injectables and biosimilars in the filing stages or development stage, which is expected to continue to support the strong product pipeline, going forward.

Global leadership in several API segments, including cephalosporins and CVS drugs – Lupin has been a global leader in the cephalosporins (third-generation antibiotics), anti-tuberculosis (anti-TB) and cardiovascular space for over 15 years. It remains one of the largest suppliers of anti-TB products to the World Health Organization's (WHO) global drug facility. It is the only company pre-qualified by WHO globally for its anti-TB APIs as well as formulations.

Strong liquidity position and robust financial profile – The net debt of the company significantly reduced to Rs. 246.8 crore as on September 30, 2021⁶ from Rs. 5,397.7 crore as on March 31, 2019, following the divestment of its Japan operations as proceeds were primarily used for debt repayment. The financial profile of Lupin remains robust as evinced by net gearing of 0.02 times and total outside liabilities vis-à-vis tangible net worth (TOL/TNW) of 0.9 times as on September 30, 2021. The coverage indicators also remain comfortable with interest cover of 22.5 times in H1 FY2022 and net debt to OPBDITA of 0.2 times as on September 30, 2021. Lupin's liquidity position is strong, marked by unencumbered cash and liquid investments of Rs. 3,305.5 crore as on September 30, 2021. ICRA notes that the company will utilise the existing liquidity to repay the Glumetza litigation settlement. However, the liquidity is additionally supported by Lupin's (standalone) unutilised bank facilities of Rs. 1,729.6 crore as on September 30, 2021.

⁴ Department of Justice

⁵ Active Pharmaceutical Ingredient

⁶ Total debt includes leased liability of Rs. 317.1 crore as on Sept 30, 2021

Credit challenges

Weakened financial performance and modest profitability indicators due to subdued revenue growth in key US market and extraordinary items – Lupin has been witnessing headwinds in the US market on account of fewer limited competition launches, weaker-than-expected performance of speciality product (Solosec), slower than expected ramp-up of Albuterol, one-time restructuring costs in Q2 FY2022 as well as the price erosion (mid-high single digits in H1 FY2022) in its base generics business on account of increased competition. The US region witnessed increased competitive pressures on its base portfolio and failure to supply penalties in Q1 FY2022 offset by improving traction for Albuterol, gBrovana and few base products in Q2 FY2022 leading to 5.6% YoY growth in H1 FY2022. Lower gross margins, coupled with increasing energy costs and higher logistic/freight costs, led to a moderated OPM (13.7% in H1 FY2022), excluding the milestone income received from Boehringer Ingelheim (\$50 million) in Q1 FY2022. The OPM, including the milestone income, was recorded at 18.2% in H1 FY2022. Furthermore, Lupin's net margins and return on capital employed declined in H1 FY2022 owing to impairment expenses on Solosec and sizeable provisions made towards the litigation settlement of Glumetza (Rs. 1,879.6 crore to be paid by December 2021). The company reported net losses of Rs. 1,546.9 crore for H1 FY2022.

Pending resolution of regulatory non-compliances, ongoing industry-wide investigations and litigations as well as exposure to regulatory risks – The company is yet to resolve the warning letters issued by the USFDA to its Goa, Pithampur Unit-II (Madhya Pradesh), Mandideep (Madhya Pradesh) and Somerset (USA) plants as well as the OAI status for its Tarapur (Maharashtra) plant. The rating also factors the provision made by the company in Q2 FY2022 and expected outflow to be made toward Glumetza, a drug for treatment of diabetes by December 2021. ICRA does not expect a material impact of the transaction on the company given its robust financial profile. Furthermore, ICRA will continue to monitor the resolution of the ongoing industry-wide investigation (including Lupin) by the anti-trust division of the US DoJ pertaining to price fixing and price collusion allegations as well as other product litigations. The operations of the company also remain exposed to regulatory risks, arising out of the greater scrutiny by regulatory agencies, including the USFDA.

Vulnerability of profitability to foreign exchange fluctuations – The company's profitability remains vulnerable to foreign exchange fluctuations on account of its foreign operations as well as foreign currency borrowings, though it hedges the same through foreign exchange forward contracts.

Liquidity position: Strong

The liquidity position of Lupin is **strong**, marked by consolidated cash and bank balances, and liquid investments of Rs. 3,305.5 crore as on September 30, 2021 (of which Rs. 2,298.1 crore were at the standalone level). The liquidity is additionally adequately supported by its (standalone) unutilised bank facilities of Rs. 1,729.6 crore as on September 30, 2021. The cash flow generation of the company is also expected to improve over the next few quarters, aided by ramp up in its US and India businesses, its continued cost control initiatives and stable working capital cycle. Moreover, it has no long-term debt repayment obligations, while capital expenditure is estimated at around Rs. 500 crore in FY2022 and Rs. 650 crore in FY2023.

Rating sensitivities

Positive factors – Not applicable

Negative factors – Negative pressure on the rating could emerge if there is a weakening in the company's liquidity position due to aggressive organic or inorganic capital expenditure or increased working capital intensity of operations. Delay in resolution of any regulatory non-compliance issued to Lupin for its products and/or manufacturing facilities, thereby impacting its product launches and thus revenues and profitability, would also be key monitorables. Moreover, any adverse outcome of the ongoing investigations/litigations would remain an event risk, and the impact of such investments on its business and credit profile would be monitored on a case-by-case basis.

Analytical approach

Analytical Approach	Comments
Applicable Rating Methodologies	Corporate Credit Rating Methodology Rating Methodology for Entities in the Pharmaceutical Industry
Parent/Group Support	Not applicable
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of Lupin Limited. As on September 30, 2021, the company had 26 subsidiaries and one joint venture company, which are enlisted in Annexure-2.

About the company

Lupin was founded in 1968 by the Late Dr. Desh Bandhu Gupta, the father of the current managing director, Mr. Nilesh Gupta. Dr. Gupta had bought the Lupin trademark from Charak Pharmaceuticals. Set up originally as a proprietary concern, Lupin was converted into a private limited company in 1972 and became a public limited company in 1992. In June 2001, it was 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. The company's business mix can be broadly divided into two segments—formulations (accounted for 89.2% of consolidated revenues in H1 FY2022) and APIs (6.2%). The rest of its revenues was generated by Lupin's new chemical entity licensing income of 4.5% in H1 FY2022. In terms of geographic presence, Lupin derived 33.5% of its H1 FY2022 formulations sales from North America, another 38.6% from India, 8.3% from growth markets and another 7.4% from the Europe, Middle East and Africa (EMEA) region.

As per the company, it is the third largest pharmaceutical player in the US by prescriptions (IQVIA MAT, September 2021) and the sixth largest company in the IPM (IQVIA MAT, September 2021).

Key financial indicators (audited)

Consolidated	FY2020	FY2021	H1 FY2022*
Operating Income (Rs. crore)	15566.9	15072.0	8390.7
PAT (Rs. crore)	-273.7	1226.6	-1546.9
OPBDIT/OI (%)	16.4%	17.0%	18.2%
PAT/OI (%)	-1.8%	8.1%	-18.4%
Total Outside Liabilities/Tangible Net Worth (times)	1.0	0.7	0.9
Total Debt/OPBDIT (times)	2.6	2.0	1.2
Interest Coverage (times)	7.0	18.3	22.5

PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation *unaudited

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current Rating (FY2022)				Chronology of Rating History for the past 3 years				
		Type	Amount Rated (Rs. crore)	Amount Outstanding (Rs. crore)	Date & Rating in		Date & Rating in FY2021	Date & Rating in FY2020		Date & Rating in FY2019
					Nov 10, 2021	Sept 24, 2021*		Nov 20, 2019	Apr 5, 2019	
1	Fund-based Facilities	Short-term	-	-	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+&	[ICRA]A1+ &
2	Non-fund Based Facilities	Short-term	-	-	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+&	[ICRA]A1+ &
3	Fund based/Non-fund based limits	Short-term	2678.0	-	[ICRA] A1+	-	-	-	-	-
4	Fund-based Facilities	Long-term	-	-	-	-	-	-	-	[ICRA]AAA&
5	Non-fund Based Facilities	Long-term	-	-	-	-	-	-	-	[ICRA]AAA&
6	Non-Convertible Debenture	Long-term	-	-	-	-	-	-	-	[ICRA]AAA&; withdrawn

&= Under watch with developing implications

* Rating outstanding

Complexity level of the rated instruments

Instrument	Complexity Indicator
Short-term- fund based/non-fund based limits	Simple

The Complexity Indicator refers to the ease with which the returns associated with the rated instrument could be estimated. It does not indicate the risk related to the timely payments on the instrument, which is rather indicated by the instrument's credit rating. It also does not indicate the complexity associated with analyzing an entity's financial, business, industry risks or complexity related to the structural, transactional, or legal aspects. Details on the complexity levels of the instruments, is available on ICRA's website: www.icra.in

Annexure-1: Instrument details

Banker Name	Instrument Name	Date of Issuance	Coupon Rate	Maturity	Amount Rated (RS Crore)	Current Rating and Outlook
Central Bank of India	Fund based/Non-fund Based Facility	NA	NA	NA	200	[ICRA]A1+
Bank of Baroda	Fund based/Non-fund Based Facility	NA	NA	NA	100	[ICRA]A1+
State Bank of India	Fund based/Non-fund Based Facility	NA	NA	NA	50	[ICRA]A1+
Citibank	Fund based/Non-fund Based Facility	NA	NA	NA	550	[ICRA]A1+
HSBC	Fund based/Non-fund Based Facility	NA	NA	NA	100	[ICRA]A1+
Standard Chartered Bank	Fund based/Non-fund Based Facility	NA	NA	NA	60	[ICRA]A1+
ICICI Bank	Fund based/Non-fund Based Facility	NA	NA	NA	300	[ICRA]A1+
Kotak Mahindra Bank	Fund based/Non-fund Based Facility	NA	NA	NA	300	[ICRA]A1+
JP Morgan Chase Bank	Fund based/Non-fund Based Facility	NA	NA	NA	185	[ICRA]A1+
MUFG Bank	Fund based/Non-fund Based Facility	NA	NA	NA	185	[ICRA]A1+
Mizuho Bank	Fund based/Non-fund Based Facility	NA	NA	NA	100	[ICRA]A1+
Bank of America	Fund based/Non-fund Based Facility	NA	NA	NA	398	[ICRA]A1+
Sumitomo Mitsui Banking Corporation	Fund based/Non-fund Based Facility	NA	NA	NA	100	[ICRA]A1+
Axis Bank	Fund based/Non-fund Based Facility	NA	NA	NA	50	[ICRA]A1+

Source: Company

Annexure-2: List of entities considered for consolidated analysis

Company Name	Lupin's Ownership	Consolidation Approach
Lupin Pharmaceuticals, Inc.	100.00%	Full Consolidation
Hormosan Pharma GmbH	100.00%	Full Consolidation
Pharma Dynamics (Proprietary) Limited	100.00%	Full Consolidation
Lupin Australia Pty Limited	100.00%	Full Consolidation
Nanomi B.V. (formerly known as Lupin Holding B.V.)	100.00%	Full Consolidation
Lupin Atlantis Holdings SA	100.00%	Full Consolidation
Multicare Pharmaceuticals Philippines Inc.	51.00%	Full Consolidation
Generic Health Pty Limited	100.00%	Full Consolidation
Bellwether Pharma Pty Limited	100.00%	Full Consolidation
Lupin Healthcare (UK) Limited [formerly Lupin (Europe) Limited]	100.00%	Full Consolidation
Lupin Pharma Canada Limited	100.00%	Full Consolidation
Lupin Healthcare Limited	100.00%	Full Consolidation
Lupin Mexico S.A. de C.V.	100.00%	Full Consolidation
Lupin Philippines Inc.	100.00%	Full Consolidation
Generic Health SDN. BHD.	100.00%	Full Consolidation
Lupin Inc.	100.00%	Full Consolidation
Laboratorios Grin S.A. de C.V.	100.00%	Full Consolidation
Medquímica Indústria Farmacêutica LTDA	100.00%	Full Consolidation
Novel Laboratories	100.00%	Full Consolidation

Company Name	Lupin's Ownership	Consolidation Approach
Lupin Research Inc.	100.00%	Full Consolidation
Lupin Latam, Inc.	100.00%	Full Consolidation
Lupin Europe GmbH	100.00%	Full Consolidation
Lupin Management Inc (Formerly Lupin IP Ventures Inc.	100.00%	Full Consolidation
Lupin Biologics Limited (India) (with effect from 28 January 2021)	100.00%	Full Consolidation
Lupin Oncology Inc. (USA) (with effect from 15 March 2021)	100.00%	Full Consolidation
Lupin Digital Health Limited (India) (with effect from 21 May 2021)	100.00%	Full Consolidation
Lupin Foundation (India)	100.00%	Full Consolidation
Joint Venture		
YL Biologics Limited	45.00%	Equity method

Source: Lupin Quarter Result for Q2 FY2022

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