

January 25, 2021

## Lupin Limited: Rating reaffirmed

### 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	1,100.0	[ICRA]A1+; re-affirmed
Short-term, Non-fund Based Limits	400.0	400.0	[ICRA]A1+; reaffirmed
<b>Total</b>	<b>1,500.00</b>	<b>1,500.00</b>	

\*Instrument details are provided in Annexure-1

## Rationale

The rating continues to derive comfort from Lupin Limited's (Lupin's) robust liquidity position, its strong business profile and geographically diversified revenue mix, with an established position in the key US and Indian pharmaceutical markets.

The financial performance of Lupin remained subdued in FY2020 and H1 FY2021, due to its muted performance in the US market. This, in turn, was due to fewer limited competition product launches and weaker-than-expected performance of its key speciality product, Solosec, which was severely impacted during the Covid-19 pandemic owing to reduced doctor visits. Lupin also undertook its second impairment (of \$227 million) in the acquired Gavis' portfolio in FY2020, owing to its lower-than-expected returns. While Lupin's domestic formulations business continued to outperform the Indian pharmaceutical market (IPM) with respect to chronic therapies in FY2020 and H1 FY2021, sharp decline in acute therapies amid reduced patient footfalls due to the pandemic, adversely impacted its revenues in H1 FY2021. Coupled with high overheads and continued research and development (R&D) expenses, this impacted its operating profit margin (OPM) in H1 FY2021. Despite this, the credit profile of the company remained adequately supported by JPY 33,328 million (~\$300 million) cash proceeds received from the divestment of its Japan operations, which were used for debt prepayment. The financial profile of the company is strong as evinced in net debt/OPBDITA of 0.8x as on September 30, 2020 and interest cover of 13.7 times in H1 FY2021. The liquidity position also remains strong, underpinned by sizeable cash and bank balances as well as liquid investments and unutilised working capital limits.

Lupin's near-term revenue outlook is healthy, with expected ramp-up of its recently launched albuterol (inhalation) and levothyroxine (thyroid) products as well as pick-up in revenues for its domestic formulations. 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, 2020, Lupin had 156 ANDAs<sup>1</sup> pending approval, including 46 first-to-files (FTFs).

Lupin's ability to maintain a healthy product portfolio in the US market and timely launch its limited competition products are critical for its revenue growth and profitability. ICRA notes the pending resolution of regulatory actions, including three warning letters and two official action indicated (OAI) status issued to five of Lupin's plants. Furthermore, the resolution of the ongoing industry-wide investigation by the anti-trust division of the US DoJ<sup>2</sup> pertaining to price-fixing and price-collusion allegations as well as other litigations is also pending. Lupin's profitability remains vulnerable to foreign exchange

<sup>1</sup> Abbreviated new drug applications

<sup>2</sup> Department of Justice

fluctuations on account of its foreign operations and foreign currency borrowings, though it hedges the same 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** – Lupin’s revenue profile is diversified across regulated and non-regulated markets, with the US accounting for 36% of its total sales in H1 FY2021. It has a well-established presence in the US generics market and ranks third<sup>3</sup> in terms of generic sales in the US. It is the fifth<sup>4</sup> largest player in the domestic formulations segment, which contributed 36% to its total sales in H1 FY2021. Lupin’s API<sup>5</sup> manufacturing capabilities are predominantly focussed on its captive requirements for formulations with ~90% of its APIs being consumed in-house. Sales from APIs contributed ~11% to its total consolidated revenues in H1 FY2021.

**Domestic formulations business continuously outperformed IPM chronic market growth** – Lupin’s domestic formulations business has consistently outperformed the IPM chronic market growth, with the company registering a compounded annual growth rate (CAGR) of 14% for its chronic portfolio during the last five years ended September 2020 vis-à-vis the industry growth of 11%.

**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 inhalation products, injectables and biosimilars), which are expected to provide a fillip to its revenues in the medium term. As on September 30, 2020, Lupin had 156 ANDAs pending approval, including 46 FTFs, of which 16 are exclusive opportunities. In August 2020, Lupin launched its key limited competition inhalation product, albuterol, ramp up of which is expected to adequately support the revenue growth in H2 FY2021. Lupin is also looking to file its biosimilar application for Pegfilgrastim to the USFDA<sup>6</sup> by the end of Q4 FY2021/Q1 FY2022.

**Global leadership in several API segments, including cephalosporins and cardiovascular (CVS) drugs** – Lupin has been a global leader in the cephalosporins (third-generation antibiotics), anti-tuberculosis (anti-TB) and CVS space for over 15 years. It remains one of the largest suppliers of anti-TB products to the World Health Organization’s (WHO’s) 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 reduced significantly to Rs. 1,626.5 crore as on September 2020 from Rs. 5,245.8 crore as on March 2019, following the divestment of its Japan operations, which resulted in a post-tax cash inflow of JPY 33,328 million (~\$300 million). The proceeds of the divestments were primarily used for debt prepayment. The financial profile of Lupin remains robust as evinced by net gearing (net debt/ net worth) of 0.1 time and total outside liabilities vis-à-vis tangible net worth (TOL/TNW) of 0.8 time as on September 30, 2020. The coverage indicators also remain comfortable with interest cover of 13.7 times in H1 FY2021 and net debt to OPBDITA of 0.8 time as on September 30, 2020. Lupin’s liquidity position is strong, marked by unencumbered cash and bank balances and liquid investments of Rs. 2,564 crore as on September 30, 2020. The liquidity is additionally adequately supported by Lupin’s (standalone) unutilised bank facilities of Rs. 2,258 crore as on December 31, 2020.

<sup>3</sup> Source: Quintiles IMS MAT September 2020, company presentation

<sup>4</sup> Source: Quintiles September 2020, company presentation

<sup>5</sup> Active pharmaceutical ingredients

<sup>6</sup> US Food and Drug Administration

### Credit challenges

#### **Weakened financial performance and modest profitability indicators due to subdued revenue growth in key US market**

– Lupin has been witnessing headwinds in the US market on account of fewer limited competition product launches, weaker-than-expected performance of its key speciality product, Solosec, as well as the price erosion (mid-single digits in H1 FY2021) in its base generics business on account of increased competition. Lupin also undertook its second impairment (of \$227 million) in its acquired Gavis’ portfolio in FY2020, owing to its lower-than-expected returns. Lupin’s US business witnessed a YoY growth of 4% in revenues in FY2020 and a decline of 9% in H1 FY2021. This, in turn, adversely impacted the revenue growth of Lupin, which stood at 5% in FY2020 and a YoY decline of 5% in H1 FY2021. Coupled with high overheads and continued R&D expenses, this resulted in a decline in its OPM to 16.4% in FY2020 and 14.5% in H1 FY2021, and a moderation in its return on capital employed (RoCE) to 6.4% in FY2020.

#### **Pending resolution of regulatory actions, ongoing industry-wide investigations 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) and Mandideep (Madhya Pradesh) plants as well as the OAI status for its plants at Somerset (USA) and Tarapur (Maharashtra). ICRA also notes the pending resolution of the on-going industry-wide investigation by the anti-trust division of the US DOJ pertaining to price-fixing and price-collusion allegations as well as the on-going product and anti-trust 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 unencumbered cash and bank balances and liquid investments of Rs. 2,564 crore as on September 30, 2020 (of which Rs. 1,445 crore were at the standalone level). The liquidity is additionally adequately supported by its (standalone) unutilised bank facilities of Rs. 2,258 crore as on December 31, 2020. The cash flow generation of the company is also expected to improve from H2 FY2021 onwards, aided by ramp up in its US and India businesses, continued cost control initiatives being undertaken by the company and stable working capital cycle. As against this, there are long-term debt repayments of Rs. 8.8 crore in H2 FY2021 and Rs. 1,774.6 crore in FY2022, with an estimated capital expenditure (capex) spend of Rs. 370 crore in H2 FY2021 and Rs. 800 crore in FY2022.

### Rating sensitivities

**Positive factors** – Not applicable

**Negative factors** – Negative pressure on the rating could emerge if there is a sustained weakening in the company’s liquidity position due to aggressive capex or increased working capital intensity of operations. Delay in resolution of existing regulatory non-compliances or any other 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. Large debt-funded inorganic investments by the company or 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	<a href="#">Corporate Credit Rating Methodology</a> <a href="#">Methodology for Pharmaceutical Industry</a>
Parent/Group Support	Not Applicable
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of Lupin. As on March 31, 2020, the company had 26 subsidiaries and one joint venture, that are enlisted in Annexure-2.

## About the company

Lupin Limited 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 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% of Lupin's consolidated revenues in H1 FY2021) and APIs (accounted for 11% of Lupin's consolidated revenues in H1 FY2021). In terms of geographic presence, Lupin derived 40% of its H1 FY2021 formulations sales from North America, another 40% from India, 9% each from Asia Pacific (APAC) and Latin America (LATAM) and another 9% 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 2020) and the fifth largest company in the IPM (IQVIA MAT, September 2020).

### Key financial indicators (audited)

Consolidated	FY2019	FY2020	H1 FY2021*
Operating Income (Rs. crore)	14,813.5	15,566.9	7,362.9
PAT (Rs. crore)	611.7	-273.7	321.2
OPBDIT/OI (%)	18.4%	16.4%	14.5%
PAT/OI (%)	4.1%	-1.8%	4.4%
Total Outside Liabilities/Tangible Net Worth (times)	1.0	1.0	0.8
Total Debt/OPBDIT (times)	3.1	2.6	2.0
Interest Coverage (times)	9.0	7.0	13.7

\*Published H1 FY2021 results

Note: FY2019 financials are restated to reflect the divestment of Lupin's Japan operations

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

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

### Rating history for past three years

	Instrument	Current Rating (FY2021)			Chronology of Rating History for the past 3 years					
		Type	Amount Rated (Rs. crore)	Amount Outstanding (Rs. crore)	Date & Rating in Jan-25-2021	Date & Rating in FY2020		Date & Rating in FY2019	Date & Rating in FY2018	
						Nov-20-2019	Apr-5-2019	Aug-2-2018	Nov-10-2017	Oct-18-2017
1	Fund-based Facilities	Short-term	1,100.0	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+&	[ICRA]A1+&	[ICRA]A1+&	[ICRA]A1+&
2	Non-fund Based Facilities	Short-term	400.0	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+&	[ICRA]A1+&	[ICRA]A1+&	[ICRA]A1+&
3	Fund-based Facilities	Long-term	-	-	-	-	-	[ICRA]AAA&	[ICRA]AAA&	[ICRA]AAA&
4	Non-fund Based Facilities	Long-term	-	-	-	-	-	[ICRA]AAA&	[ICRA]AAA&	[ICRA]AAA&

&= Under watch with developing implications

#### 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 [click here](#)

**Annexure-1: Instrument details**

ISIN No	Instrument Name	Date of Issuance / Sanction	Coupon Rate	Maturity Date	Amount Rated (Rs. crore)	Current Rating
NA	Fund-based Facilities	-	-	-	1,100.0	[ICRA]A1+
NA	Non-fund Based Facilities	-	-	-	400.0	[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 Middle East FZ-LLC	100.00%	Full Consolidation
Lupin GmbH	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
Lupin Research Inc.	100.00%	Full Consolidation
Lupin Latam, Inc.	100.00%	Full Consolidation
Lupin Japan & Asia Pacific K.K.	100.00%	Full Consolidation
Lupin Europe GmbH	100.00%	Full Consolidation
Lupin Management Inc (Formerly Lupin IP Ventures Inc.	100.00%	Full Consolidation
<b>Joint Venture</b>		
YL Biologics Limited	45.00%	Equity method

Source: Lupin annual report FY2020

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