February 23, 2023 (Revised)

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/ Non-fund Based Limits	2,678.00	3,000.00	[ICRA]A1+ reaffirmed/assigned
Total	**2,678.00**	**3,000.00**	

**Instrument details are provided in Annexure-I*

Rationale

The rating reaffirmation of Lupin Limited (Lupin) factors in the company's strong business profile, its position as one of the leading[1] companies in the Indian pharmaceutical market (IPM), its geographically diversified revenue mix and global leadership in several API[2] segments. Moreover, Lupin's financial profile remains healthy, adequately supported by its strong liquidity position with sizeable cash equivalents and liquid investments and unutilised working capital limits. Despite some performance moderation in recent times, there has been improvement over the last two quarters, which is expected to sustain over the near to medium term, supported by a robust pipeline of limited contribution products (including inhalations and injectables), broad-based growth across key markets and fruitification of cost rationalisation initiatives taken over the past few quarters.

While the US business continued to remain impacted by the price erosion, performance over the last few quarters was supported by strong performance of products like Albuterol and Arfometerol, coupled with the acquisition of Brovana and Xopenex, and launch of Suprep in September 2022, which is expected to contribute significantly in Q3 and Q4 FY2023. Lupin has a robust pipeline of limited competition complex generics in the inhalations and injectables portfolio like gSpiriva, gDiazepam Gel, gNascobal Nasal Spray and gDarunavir, which are expected to support revenue growth over the medium term. The successful audit of the Somerset facility is also expected to expedite the new launches. As on December 31, 2022, Lupin had 167 ANDAs[3] pending approval, including 55 first-to-files (FTFs).

Revenue contribution from the domestic business remained flattish during 9M FY2023, primarily on account of loss of Cidmus from the cardiovascular portfolio and genericisation of gliptins in the anti-diabetic segment. However, during Q3 FY2023, growth of the anti-diabetic portfolio was in line with the market trend. Lupin increased the strength of its marketing executive to around 7,100 with an addition of close to 1,000 representatives during Q3 FY2023, taking the total sales force to ~9,300. Integration of the sales force over the next few quarters, coupled with improvement in the performance of chronic therapies, is expected to support the growth in domestic business, going forward.

ICRA notes the successful inspections of the Goa and Somerset manufacturing facilities over the last few quarters, which is expected to support the launch of new products in the US. However, resolutions of the Pithampur (Madhya Pradesh), Tarapur (Maharashtra) and Mandideep (Madhya Pradesh) facilities continue to remain pending. The rating also factors in the pending resolution of the ongoing industry-wide investigation by the anti-trust division of the US DoJ[4] for price-fixing and price collusion allegations as well as other litigations. Lupin's profitability remains vulnerable to foreign exchange (forex) fluctuations because of its foreign operations and foreign currency borrowings, though it hedges them through forward contracts. Large inorganic

[1] *Lupin is the third largest (IQVIA MAT, December 2022) generic player in the US by prescriptions and ranks sixth (IQVIA MAT, December 2022) in the IPM.*

[2] *Active Pharmaceutical Ingredient*

[3] *Abbreviated new drug applications*

[4] *Department of Justice*

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.

ICRA expects Lupin to maintain its healthy credit profile with strong liquidity position, aided by increasing internal accrual generation on the back of steady improvement in its margins and growth across key markets.

Key rating drivers and their description

Credit strengths

Leading player in Indian branded formulations segment – Lupin ranks sixth in the IPM with a leading position in several therapies including anti-tuberculosis (first), respiratory (second), cardiology (third) and anti-diabetic (third)[5]. While growth remained subdued during 9M FY2023 with total revenue of Rs. 4,597.4 crore, registering a 1.2% degrowth over revenues in 9M FY2022 due to the loss of Cidmus and genericisation of gliptins leading to higher competition in the anti-diabetic portfolio, the performance of the segment is expected to improve over the next few quarters supported by integration of the ~1,000 marketing executives. Lupin continues to maintain its leadership position in the chronic therapies (accounted for ~65% of the domestic revenues in FY2022), which are expected to drive growth, going forward.

Geographically diversified revenue mix – Lupin's revenue profile is well diversified with India and the US being the key markets contributing 38.5% and 32.4%, respectively, to its consolidated revenues. It has continued its growth momentum in the growth markets (Asia Pacific and Latin America) with a 26.1% YoY growth in 9M FY2023, and in Europe, Middle East and Africa (EMEA) with 15.3%. Growth markets contributed 10.8% and EMEA drove 9.2% during 9M FY2023. Lupin's API manufacturing capabilities are predominantly focussed on its captive requirements for formulations with ~90% of its APIs being consumed in-house. API sales drove 6.6% of its revenues in 9M FY2023.

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's) global drug facility. It is the only company pre-qualified by WHO globally for its anti-TB APIs as well as formulations. It enjoys large economies of scale in certain segments on account of forward integration into formulations, high bargaining power with intermediate suppliers and strong technological capabilities in API development and manufacturing. The global API market was impacted in FY2022 and 9M FY2023 by the moderation in demand for antibiotic pharmaceutical products after Covid-19 and the rise in raw material cost due to various geo-political developments over the past few quarters. However, demand seems to have improved in Q3 FY2023, coupled with some stabilisation in prices of raw materials, which has resulted in a ~13% QoQ growth in revenues from the API segment in Q3 FY2023.

Healthy financial profile and strong liquidity position – Lupin has a healthy financial profile characterised by low net gearing of 0.3 time and total outside liabilities vis-à-vis tangible net worth (TOL/TNW) of 0.8 time as on September 30, 2022. While its debt coverage metrics have witnessed some moderation in 9M FY2023 due to contraction in margins, the same are expected to strengthen over the near to medium term on the back improvement in operating margins and no material increase in debt levels. Lupin's liquidity position also remains strong, supported by improving accrual generation and cash equivalents and liquid investments of Rs. 1,342 crore and undrawn working capital limits (standalone) of Rs. 928 crore as on December 31, 2022. Going forward, in the absence of any major debt-funded capex, the capital structure and credit metrics are expected to strengthen in line with the growth in revenues and profitability.

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[5] *Source: Company Presentation*

Credit challenges

Contraction in profit margins due to pricing pressure in the US market leading to moderation in accrual generation; however, steady improvement expected over the near to medium term – Continued pricing pressures in the US market coupled with moderation in new launch momentum due to regulatory observations from USFDA[6] for some of its key facilities and inventory write-offs impacted Lupin's profitability in the US market over the past few quarters. Moreover, loss of Cidmus in FY2023 and generecisation of gliptins also impacted the revenue and profitability of the domestic business. However, with increasing efforts for cost optimisation including optimisation of R&D spend, discontinuation of low margin products in US and strong performance of new launches, it has witnessed a sequential improvement in operating margins from 6.2% in Q1 FY2023 to 11.9% in Q3 FY2023. While margins remained moderate at 9.1% in 9M FY2023 (against 13.1% in FY2022), steady improvement in margins is expected over the near to medium term supported by a healthy launch pipeline of limited competition complex generics and continued growth momentum across growth markets, EMEA and rest of the world (RoW) markets. The pipeline of new launches includes gSpiriva, gDiazepam Gel, gNascobal Nasal Spray and gDarunavir wherein the company either has exclusivity or first-to-market position. However, timely launches remain a key to recovery of margins.

Exposure to regulatory risks and litigations – Lupin's operations remain exposed to regulatory risks of greater scrutiny by regulatory agencies, including the USFDA as well as pricing controls in the domestic market. ICRA notes the ~18% coverage of its domestic formulations under NLEM, which though has benefitted from the 10.7% increase in prices allowed for FY2023, remains exposed to future price control measures or addition of more products in the list of NLEM drugs. Lupin was able to successfully resolve the regulatory observations from the US FDA pertaining to its Goa and Somerset facilities, which have been important for supplies to the US market. However, the company is yet to resolve the warning letters issued by the USFDA to its Pithampur Unit-II (Madhya Pradesh), Tarapur (Maharashtra) and Mandideep (Madhya Pradesh) facilities. Furthermore, it is part of the ongoing industry-wide investigation by the anti-trust division of the US DoJ pertaining to price fixing and price collusion allegations as well as other product litigations. ICRA will continue to monitor the impact of any adverse outcome of the litigation on the credit profile of the company.

Vulnerability of profitability to forex fluctuations – Lupin's profitability remains vulnerable to foreign exchange fluctuations on account of its foreign operations as well as foreign currency borrowings; although it hedges the same through foreign exchange forward contracts.

Environmental and Social Risks

Environmental concerns – Lupin does not face any major physical climate risk. However, it remains exposed to tightening environmental regulations with regard to breach of the waste and pollution norms, which can lead to an increase in operating costs or capital investments. To address the environmental risks Lupin has taken a variety of energy-efficient measures, such as energy-efficient lighting, pumping and utilization of renewable energy. Lupin has also taken commitments for decarbonization to reduce its Scope 1 and Scope 2 greenhouse gas (GHG) emissions by 15% from 2019-20 levels by 2030, targets for recycling 50% of total water withdrawal in its operations by 2025 and to ensure that 60% of the hazardous waste generated in its Indian operations will be sent to cement plants for co-processing by 2025.

Social concerns – The industry faces social risks related to product safety and the associated litigation risks, access to qualified personnel for R&D and process engineering, and maintenance of high manufacturing compliance standards. Further, government intervention related to price caps/control also remains a social risk faced by entities in the pharmaceutical industry. As of December 31, 2022, around 384 drugs were covered under NLEM, falling under the ambit of Drug Price Control Order; and the Government may bring more such drugs under price control. Lupin had ~18% coverage of its domestic formulations under NLEM as of December 31, 2022.

[6] *United States Food and Drugs Administration*

Liquidity position: Strong

Lupin's liquidity position remains **strong**, marked by consolidated cash and bank balances, and liquid investments of ~Rs. 1,342 crore as on December 31, 2022. The liquidity is additionally adequately enhanced by its unutilised bank facilities (standalone) of Rs. 928 crore as on December 31, 2022 and minimal long-term debt repayment obligations of Rs. 47.3 crore p.a. from FY2024 to FY2026. Moreover, the company's cash flow generation has improved in recent quarters, with the momentum expected to sustain over the near to medium term, supported by broad-based growth across key markets and its continued cost control initiatives. Capex is also estimated to be modest at around Rs. 600.0 crore p.a., to be funded through internal accruals.

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 capex 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 December 31, 2022, the company had 27 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 93.4% of consolidated revenues in 9M FY2023) and APIs (6.6%). In terms of geographic presence, Lupin derived 32.4% of its 9M FY2023 sales from North America, another 38.5% from India, 10.8% from growth markets and another 9.2% from the EMEA region.

As per the company, it is the third largest pharmaceutical player in the US by prescriptions (IQVIA MAT, December 2022) and the sixth largest company in the IPM (IQVIA MAT, December 2022).

Key financial indicators (audited)

Lupin - Consolidated	FY2021	FY2022
Operating income	15072.0	16,473.9
PAT	1226.6	-1509.7
OPBDIT/OI	17.0%	13.1%
PAT/OI	8.1%	-9.2%
Total outside liabilities/Tangible net worth (times)	0.7	0.8
Total debt/OPBDIT (times)	2.0	1.9
Interest coverage (times)	18.3	15.2

PAT: Profit after tax; OPBDIT: Operating profit before depreciation, interest, taxes and amortisation; Amount in Rs crore

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current rating (FY2023)				Chronology of rating history for the past 3 years				
		Type	Amount rated (Rs. crore)	Amount outstanding (Rs. crore)	Date & rating in FY2023	Date & rating in FY2022		Date & rating in FY2021	Date & rating in FY2020	
					Feb 23, 2023	Nov 10, 2021	Sep 24, 2021	Jan 25, 2021	Nov 20, 2019	Apr 05, 2019
1	**Fund-based Facilities**	Short-term	-	-	-	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+ &
2	**Non-fund Based Facilities**	Short-term	-	-	-	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+ &
3	**Fund based/Non-fund based limits**	Short-term	3,000.0	-	**[ICRA]A1+**	[ICRA]A1+	-	-	-	-

&: Rating Watch with Developing Implications

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 analysing 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 are available on ICRA's website: Click Here

Annexure I: Instrument details

ISIN	Instrument Name	Date of Issuance	Coupon Rate	Maturity	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Fund-based/ non-fund based facility	NA	NA	NA	3,000.0	[ICRA]A1+

Source: Company

[Please click here to view details of lender-wise facilities rated by ICRA]

Annexure II: List of entities considered for consolidated analysis

Company Name	Lupin 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 Diagnostics (formerly 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
Lupin Research Inc.	100.00%	Full Consolidation
Avenue Coral Springs LLC (with effect from 29 November 2021)	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)	100.00%	Full Consolidation
Lupin Oncology Inc. (USA)	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
Southern Cross Pharma Pty Ltd (with effect from 3 Feb 2022)	100.00%	Full Consolidation
Joint Venture		

Company Name	Lupin Ownership	Consolidation Approach
YL Biologics Limited	45.00%	Equity method

Source: Lupin quarterly result for Q3 FY2023

Corrigendum

Document dated February 23, 2023 has been corrected with revisions as detailed below:
Revisions: - Page 2 – Typographical error in the second paragraph on page 2 has been corrected

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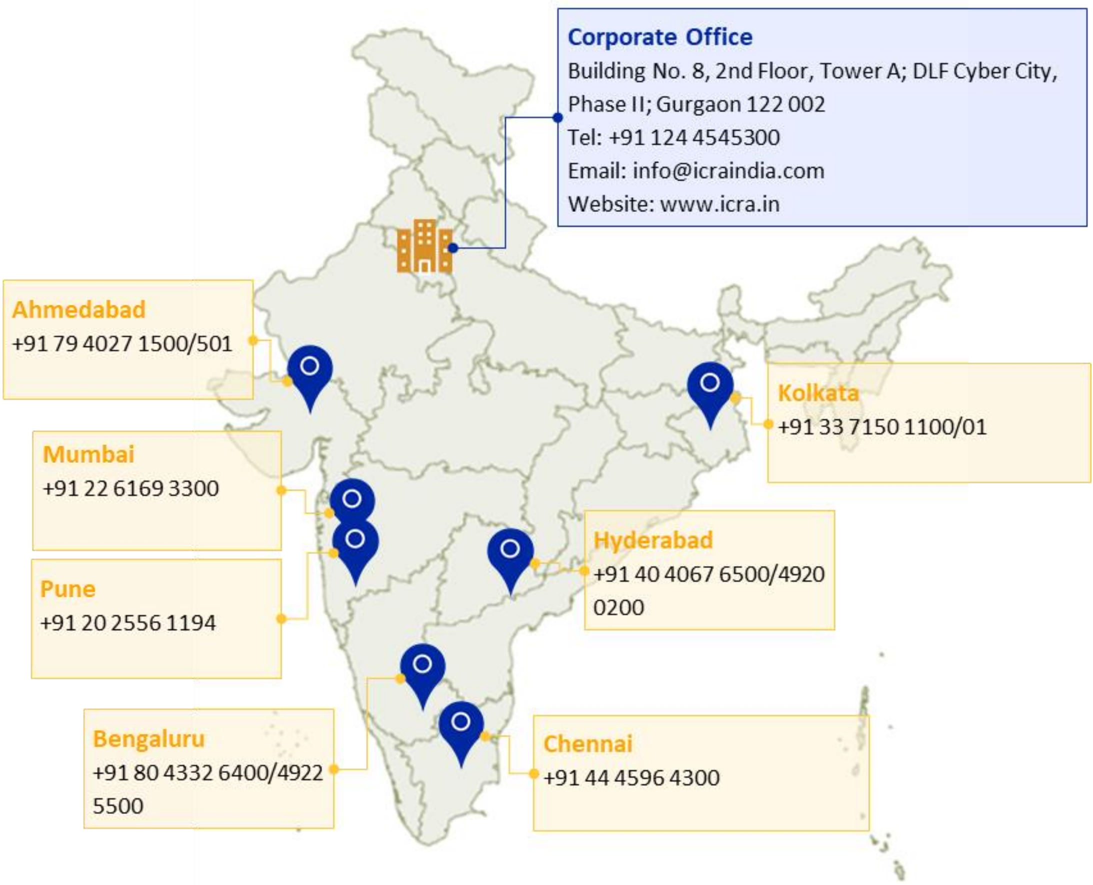

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