

April 25, 2024

Lupin Manufacturing Solutions Limited: Rating assigned

Summary of rating action

Instrument*	Current Rated Amount (Rs. crore)	Rating Action
Short-term – fund-based/non-fund based facilities	100.00	[ICRA]A1+; assigned
Total	100.00	

*Instrument details are provided in Annexure-I

Rationale

While assigning the rating for Lupin Manufacturing Solutions Limited (LMSL), ICRA has taken a consolidated view of Lupin Limited (Lupin) and its wholly-owned subsidiary, LMSL, given their common management and significant operational and financial linkages between them.

The rating reaffirmation of Lupin factors in the strengthening of the company's financial profile supported by strong internal accrual generation on the back of healthy revenue growth and improvement in its operating margins (OPM); and ICRA's expectation of sustenance of the same over the near term. Lupin reported a 23.2% YoY growth in its revenue to Rs. 15,050.0 crore in 9M FY2024 from Rs. 12,211.6 crore in 9M FY2023 aided by new product launches and broad-based growth across key markets, while its OPM improved to 18.6% from 9.1% in 9M FY2023 (10.8% in FY2023) over the same period, aided by the growing contribution of complex generics products (including inhalations and injectables) and successful implementation of various cost optimisation initiatives. Higher internal accrual generation has led to reduced reliance on debt and strengthening of the company's debt protection metrics and liquidity position. The rating also continues to factor in Lupin's strong business profile, its position as one of the leading¹ companies in the Indian pharmaceutical market (IPM), its geographically diversified revenue mix and global leadership in several API² segments.

Lupin's revenue from the US business grew by 38.2% to Rs. 5,345.6 crore in 9M FY2024 supported by volume-led growth in the base business, increased pace of new product launches on account of clearance of a warning letter issued to its facility at Pithampur, Madhya Pradesh, and increasing contribution from the complex generics portfolio including Tiotropium (gSpiriva), which was launched in August 2023. The contribution from the inhalation portfolio has increased significantly to around 42% of Lupin's revenues from the US business and 25% of its global revenues. Coupled with moderation in price erosion in the oral solids portfolio, this has also resulted in improvement in Lupin's OPM. Further, ramp up in sales of new products like Tiotropium and Prolensa, and a strong pipeline of complex generics including injectables like Glucagon and Fosphenytoin, are expected to continue to support Lupin's US business.

Revenue contribution from the domestic business also grew by 10.0% during 9M FY2024, on account of healthy growth across key therapy areas including respiratory, gastrointestinal and gynaecology. Growth in anti-diabetes therapy has remained moderated across the market, including for Lupin, owing to a few patents expiring in the past; however, Lupin performed better than the market in the therapy area. Moreover, with a couple of more products going off-patent in FY2025, performance of the anti-diabetes portfolio is expected to continue to remain moderated. However, the company is expected to continue to outperform the growth in the IPM going forward as well.

ICRA notes the successful inspection of the manufacturing facility at Pithampur, which is expected to support the launch of new products in the US. While resolution of warning letters issued to the facilities at Tarapur (Maharashtra) and Unit -1 in Mandideep (Madhya Pradesh) is still pending, ICRA notes that these facilities do not contribute significantly to Lupin's US

¹ Lupin is the third largest (IQVIA MAT, December 2023) generic player in the US by prescriptions, and ranks seventh (IQVIA MAT, December 2023) in the IPM.

² Active Pharmaceutical Ingredient

business. The rating also factors in the pending resolution of the ongoing industry-wide investigation by the anti-trust division of the US DoJ³ for price-fixing and price collusion allegations as well as other litigations. Moreover, 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 investments by the company will also 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.

LMSL was incorporated in July 2023 and two of Lupin's API manufacturing facilities at Dabhasa (Gujarat) and Visakhapatnam (Andhra Pradesh) along with select R&D operations, including fermentation, at Lupin Research Park, Pune (Maharashtra), were transferred to this entity as part of a business transfer agreement between the two companies. LMSL was established for increasing the Group's focus on improving the scale and profitability of its API business by exploring opportunities in the CDMO⁴ space and new product launches. While LMSL currently has a modest scale of operations and is likely to report a net loss in FY2024, its financial performance is expected to improve considerably over the near to medium term.

Key rating drivers and their description

Credit strengths

Leading player in US and domestic markets; growing contribution of complex generics in inhalation and injectables – Lupin ranks seventh in the IPM with a leading position in several therapies including anti-tuberculosis (first), respiratory (second), cardiology (third) and anti-diabetic (third)⁵. Moreover, performance of the US business has improved on account of increased pace of new product launches and improved product mix with a higher share of complex generics (including inhalations and injectables). While the injectables portfolio of the company is still evolving, its inhalations portfolio has become a significant contributor driving ~42% of its revenues from the US business and 25% of its global revenues. This has also supported the improvement in the company's OPM. In India, despite some moderation in the growth of the anti-diabetes portfolio, Lupin is expected to continue to outperform the growth of the IPM supported by higher focus on other therapies and products.

Geographically diversified revenue mix – Lupin's revenue profile is well diversified with India and the US being the key markets contributing 34% and 36%, respectively, to its consolidated revenues during 9M FY2024. Healthy performance in these markets with a growth of 38% in the US business and 10% in the Indian business has supported its overall revenue growth. Moreover, the growth markets⁶ and EMEA⁷ contributed 9% each to Lupin's consolidated revenues during 9M FY2024, with revenues from these markets growing by 2% and 27% YoY, respectively. Lupin also derived around 6% of its 9M FY2024 revenues from its API business. Its API manufacturing capabilities are predominantly focussed on its captive requirements for formulations with ~90% of its APIs being consumed inhouse. However, it has now carved out two of its API manufacturing sites at Dabhasa and Visakhapatnam, along with select R&D operations, including fermentation, at Lupin Research Park, Pune, into a separate wholly-owned subsidiary, Lupin Manufacturing Solutions Limited. This will help put more focus on its API business and improve its scale and profitability.

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 and 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 API business of Lupin grew by 12% YoY to Rs. 883.4 crore in 9M FY2024. Further, with the incorporation of LMSL and having higher focus on improving the performance of the API business, the segment is expected to improve its performance over the medium term.

³ Department of Justice

⁴ Contract development and manufacturing organisation

⁵ Source: Company presentation

⁶ Asia Pacific and Latin America

⁷ Europe, Middle East and Africa

Healthy financial profile and strong liquidity position – Lupin has a healthy financial profile characterised by sizeable net worth and strong accrual generation aided by healthy revenue growth and improvement in margins. Moreover, its debt levels have also reduced to net debt (including lease liability) of Rs. 2,193.2 crore as on September 30, 2023, from Rs. 2,823.9 crore as on March 31, 2023. Consequently, its coverage metrics have also strengthened, as marked by estimated net Debt/OPBDITA of 0.1-0.3 times for FY2024 as against 1.6 times for FY2023. The expectation of continued healthy accrual generation, reduced reliance on external debt as well as build-up of surplus cash/liquid investment balances will likely result in negative net debt position for the company in FY2025, in the absence of any major debt-funded capex. Capitalisation and coverage indicators are also expected to improve further, aided by strong cashflows and further reduction in its debt. Lupin's liquidity position also remains strong, supported by strong accrual generation, estimated cash equivalents and liquid investments of ~Rs. 1,200-1,300 crore as on March 31, 2024, and sizeable undrawn working capital limits.

Credit challenges

Base US business continues to remain competitive – The US generic market has remained competitive with continued pricing pressure across various product categories. This has impacted the performance of the US generics business of several generic players in the market, including Lupin. While regular product launches in the market can mitigate the impact to a certain extent, pressure is expected to continue on Lupin's business in the US. Increasing contribution of complex generics (which experience lower pricing pressure than oral solids) to Lupin's US business is also expected to mitigate the impact to a certain extent. This is also evident from the improvement in the company's OPM to 18.6% in 9M FY2024 from 9.1% in 9M FY2023, partly driven by higher contribution from the inhalation portfolio (~42% of Lupin's US business in 9M FY2024).

Exposure to regulatory risks and litigations – Lupin's operations remain exposed to regulatory risks of greater scrutiny by regulatory agencies, including the USFDA⁸, as well as pricing controls in the domestic market. ICRA notes the ~15-16% coverage of its domestic formulations under NLEM⁹, which 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 USFDA pertaining to its Pithampur facility, which has been important for supplies to the US market. However, the company is yet to resolve the warning letters issued by the USFDA to its facilities at Tarapur and Unit-1 in Mandideep. 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. 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.

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

Liquidity position: Strong

Lupin's liquidity position remains **strong**, marked by estimated consolidated cash and bank balances, and liquid investments of Rs. 1,200-1,300 crore as on March 31, 2024. The liquidity is additionally adequately enhanced by its unutilised bank facilities (standalone) of ~Rs. 2000-2,200 crore as on the same date. 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 successful implementation of cost control initiatives. Regular capex is also estimated to be modest at around Rs. 700-800 crore p.a., to be funded through internal accruals.

⁸ United States Food and Drug Authority

⁹ National List of Essential Medicines

Rating sensitivities

Positive factors – Not applicable.

Negative factors – Negative pressure on the rating could emerge if there is considerable and sustained weakening in the company's leverage and liquidity position due to aggressive capex or inorganic investments or increased working capital intensity of operations. Any adverse impact of any regulatory developments, thereby impacting Lupin's product launches and, thus, revenues and profitability, would also be a key monitorable.

Analytical approach

Analytical Approach	Comments
Applicable rating methodologies	Corporate Credit Rating Methodology Rating Methodology for entities in the pharmaceuticals
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, 2023, the company had 27 subsidiaries and one joint venture company, which are enlisted in Annexure-II.

About the company

LMSL is a wholly-owned subsidiary of Lupin, which was incorporated in July 2023 to carve out two of Lupin's API manufacturing sites at Dabhasa and Visakhapatnam, along with select R&D operations, including fermentation, at Lupin Research Park, Pune.

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 92.6% of consolidated revenues in 9M FY2024) and APIs (6.0%). In terms of geographic presence, Lupin derived 36.2% of its 9M FY2024 sales from North America, another 34.2% from India, 8.9% from growth markets and 9.4% from the EMEA region.

As per the company, it is the third largest pharmaceutical player in the US by prescriptions (IQVIA MAT, December 2023) and the seventh largest company in the IPM (IQVIA MAT, December 2023).

Key financial indicators (audited)

Lupin - Consolidated	FY2022	FY2023	9M FY2024*
Operating income	16,473.9	16,719.2	15,050.0
PAT	-1509.7	447.7	1,567.4
OPBDIT/OI	13.1%	10.8%	18.6%
PAT/OI	-9.2%	2.7%	10.4%
Total outside liabilities/Tangible net worth (times)	0.8	0.8	-
Total debt/OPBDIT (times)	1.9	2.5	-
Interest coverage (times)	15.2	6.6	-

Source: Company, ICRA Research; All ratios as per ICRA's calculations; Amount in Rs. Crore; 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	Type	Current rating (FY2025)			Chronology of rating history for the past 3 years			
		Amount rated (Rs. crore)	Amount outstanding as of Dec 31, 2023 (Rs. crore)	Date & rating in FY2025	Date & rating in FY2024	Date & rating in FY2023	Date & rating in FY2022	
1	Fund based/Non fund based limits	Short term	100.00	-	April 25, 2024	-	-	-
				[ICRA]A1+	-	-	-	-

Complexity level of the rated instruments

Instrument	Complexity Indicator
Short-term - fund-based/non-fund based facilities	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	Short-term - fund-based/non-fund based facilities	NA	NA	NA	100.00	[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

Company Name	Lupin Ownership	Consolidation Approach
Lupin Manufacturing Solutions Limited	100.00%	Full Consolidation
Lupin Life Science Limited	100.00%	Full Consolidation
Medisol S.A.S	100.00%	Full Consolidation
Lymed S.A.S	100.00%	Full Consolidation
Joint Venture		
YL Biologics Limited	45.00%	Equity method

Source: Company financial disclosures

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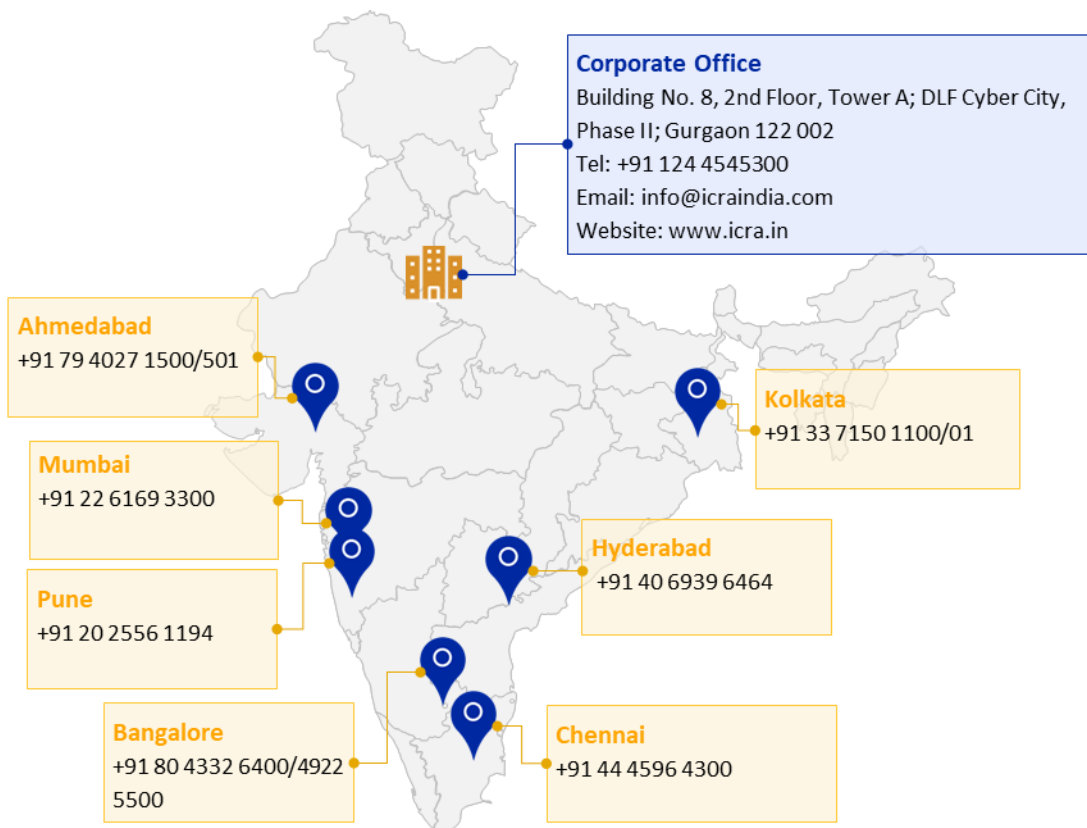
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