ICRA

November 20, 2019

Lupin Limited: Rating removed from watch with developing implications

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+, removed from rating watch with developing implications
Short-term Non-fund Based Limits	400.0	400.0	[ICRA]A1+; removed from rating watch with developing implications
Total	1,500.0	1,500.0	

**Instrument details are provided in Annexure-1*

Material event

Lupin Limited, on November 11, 2019, announced that it has approved the divestment of its entire equity interest (representing 99.82% of the issued and paid-up capital) of Kyowa Pharmaceutical Industry Co. Ltd (Kyowa) by way of sale of shares to Plutus Limited (an entity affiliated with Unison Capital partners) at an enterprise value (EV) of JPY 57,361 million (Rs.3702 crore), subject to necessary approvals including Japan Fair Trade Commission and shareholders of the company. The proposed transaction is an all cash-transaction, valued at EV/sales of 2 times and will result in post-tax net cash inflow of ~JPY 32,596 million (Rs. 2,104 crore). The transaction is expected to be concluded within FY2020.

Impact of material event

ICRA has a short-term rating of [ICRA]A1+ (pronounced ICRA A one plus) assigned to the Rs. 1,100-crore short-term fund-based limits and Rs. 400-crore short-term non-fund based limits. The rating has been removed from watch with developing implications.

Rationale

The removal of the rating watch factors in the expected strengthening of the credit profile of Lupin Limited, following the divestment of Kyowa (which accounted for 10.6% of consolidated operating income (OI) and 9.1% of OPBDITA of Lupin in FY2019), along with receipt of post-tax cash proceeds of JPY 32,596 million (Rs.2,104 crore). The proceeds are expected to be utilised mainly for paring down of the debt levels, besides providing growth capital to support Lupin's organic and inorganic initiatives in its focus markets, including US (speciality segment) and India. Following the divestment of Kyowa, its net debt stood at Rs.1,129 crore reduced from Rs. 4,362 crore as on September 30, 2019, resulting in significant improvement in the financial profile, with an expected net debt/EBITDA of less than 0.6 times as of March 2020. Besides, the divestment augurs well for the long-term profitability of Lupin Limited, given the pricing pressures being faced in Japan owing to annual price cuts by the Government to promote generics. The company shall, however, continue to have presence in Japan through its biosimilar portfolio (Etanercept, which is being launched in partnership with Nichiko), as well as other proposed launched of speciality products/complex generics.

The rating continues to derive comfort from Lupin's business profile and geographically-diversified revenue mix, with an established position in the key US and domestic pharmaceutical markets. Lupin is the sixth[1]largest player in the domestic formulations segment, with its portfolio weighted in favour of the high-margin chronic/lifestyle-related therapies. It continues to outperform the Indian pharmaceutical market (IPM). Lupin has a well-established presence in US generics market where it ranks third[2], in terms of generic sales, despite witnessing pricing pressure during the last two years. The company also has a robust pipeline of limited competition products, complex generics and biosimilars, which are expected to provide a fillip to its revenues in the medium term, given its strong research and development (R&D) capabilities. As on September 30, 2019, Lupin had 154 abbreviated new drug applications (ANDAs) pending approval, including 40 first-to-files (FTFs), of which 14 are exclusive opportunities. The liquidity position also remains strong, as evinced by its sizeable cash and bank balances and liquid investments of Rs. 4575 crore and undrawn bank limits of Rs. 1,314 crore (as on September 30, 2019).

Lupin reported a 12.4% YoY increase in revenues in H1 FY2020 led by robust 18% YoY growth in US sales, mainly supported by 90-days sales exclusivity for gRanexa. The company continued to report robust performance in the Indian region, with an 11% YoY growth in H1 FY2020. Increased revenues and higher gross margins due to favourable product mix also led to an improvement in EBITDA, with Lupin reporting an EBITDA margin of 18.2% in H1 FY2020 vis-a-vis 13.8% in H1 FY2019. Notwithstanding the YoY improvement in operating margins, it however, remained lower than pre-FY2017 levels owing to continued price erosion in the base business in US as well as lower limited competition launches. The net profit was also adversely impacted by two one-offs cumulating to Rs. 547 crore including, loss of Rs. 167 crore on divestment of shares of Kyowa Criticare Co. Ltd (KCC) and provision of US$53.5 million (Rs.379 crore), following Lupin's settlement of a lawsuit with the State of Texas in US.

Lupin's product pipeline for US remains strong, with expected ramp-of Levothyroxine in H2 FY2020 following the receipt of ANDA approval against the three reference listed drugs (RLDs). The company proposes to launch some complex products (including injectables, inhalers and biosimilars) in H2FY2020 and FY2021 as well, which is expected to adequately support revenue growth and improve profitability over the medium term. Lupin's ability to maintain a healthy product portfolio in US markets as well as the timely ramp up of the sales of its limited competition products are critical for its revenue growth and profitability and are key rating sensitivities. The rating factors in the pending resolution of the regulatory non-compliances, including warning letters issued to three of Lupin's manufacturing facilities at Goa, Pithampur (Madhya Pradesh) and Mandideep (Madhya Pradesh) as well as an official action indicated (OAI) status for its plant at Somerset (United States). These facilities account for more than 60% of Lupin's pending ANDAs with the USFDA. The rating factors in the pending resolution of the ongoing industry-wide investigation by the anti-trust division of the US Department of Justice (DOJ) pertaining to price-fixing and price-collusion allegations. Its 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. 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.

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[1] *Source: Quintiles September 2019, company presentation*

[2] *Source: Quintiles IMS MAT September 2019, company presentation*

Key rating drivers and their description

Credit strengths

Strong and well-diversified business model – Lupin's revenue profile is diversified across both branded and generic formulations in regulated as well as non-regulated markets, with the US accounting for 33% of its total sales in H1 FY2020. It has a well-established presence in US generics market and ranks third, in terms of generic sales, in US. It is the fifth largest player in the domestic formulations segment, which contributed 31% to its total sales in H1 FY2020. Lupin's API manufacturing capabilities are predominantly focussed on its captive requirements for formulations with ~90% of its APIs being consumed in-house. Sales from APIs contributed ~8% to its total consolidated revenues in H1 FY2020.

Strong pipeline of limited competition, difficult-to-manufacture products for US generics 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 the therapeutic areas of cardiovascular systems (CVS), respiratory, central nervous system (CNS), oral contraceptives (OCs) and dermatology among others. As on September 30, 2019, Lupin had 154 ANDAs pending approval including 40FTFs, of which 14 are exclusive opportunities. The company launched limited competition product-Levothyroxine in Q4 FY2019 and has recently received ANDA approval against the three reference listed drugs (RLDs), which is expected to help scale up revenues in H2 FY2020. The company also interesting line-up of limited competition products planned for FY2020 and FY2021, including Albuterol MDI, among others. Lupin proposes to commercialise its first biosimilar, Etanercept, in Japan in H2 FY2020 (in partnership with Nichiko)

Domestic formulations business has continuously outperformed IPM growth – Lupin reported 11% YoY growth in its domestic formulations sales in H1 FY2020. The domestic segment continues to outperform the IPM, with the company registering compounded annual growth rate (CAGR) of 15% for its chronic portfolio during the last three years vis-a-vis the industry growth of 11%.

Expected strengthening of credit profile, following divestment of stake in Kyowa – Lupin's credit profile is expected to strengthen following the divestment of Kyowa as the company will be primarily utilising the proceeds for debt reduction. Its net debt reduced from Rs. 4,362 crore as on September 30, 2019 to Rs.1,129 crore, resulting in significant improvement in the financial profile, with an expected net debt/EBITDA of less than 0.6 times as of March 2020.

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 CVS space for over 15 years. It continues to gain traction in its global institutional business and remains one of the largest suppliers of anti-TB products to the World Health Organisation's (WHO) global drug facility. It is the only company pre-qualified by WHO globally for its anti-TB APIs as well as formulations

Robust liquidity position – Lupin's liquidity position is strong marked by unencumbered cash and liquid investments of Rs. 4,575 crore as on September 30, 2019 and unutilised bank lines (consolidated) of Rs. 1,314 crore as of September 30, 2019.

Credit challenges

Constrained, though improving profitability over the last three years, due to pricing pressures in the key US market-

Lupin has been witnessing headwinds in its key market, US, due to price erosion in its base generics business on account of channel consolidation in US and increased competition. Its profitability was impacted in FY2018 and FY2019 by increased competition for its key molecules, including gGlumetza, gFortamet and Methergine. The company faced pricing pressure in Japan owing to the annual price cuts announced by the Government (against biennial price cuts earlier), not only for the unbranded segment, but also for long-listed products. These factors led to a decline in Lupin's OPM to20.8% in FY2018 and further to 18.2% in FY2019, with a moderation in its return on capital employed (RoCE) to 9.4% in FY2019. The company, however, launched two key limited competition products in Q4 FY2019-gRanexa (with 90 days sales exclusivity) and levothyroxine, which helped improve operating margin to 18.2% in H1 FY2020 vis-a-vis 13.8% in H1 FY2019. Timely launch of the limited competition products and its ability to garner a meaningful market share within a reasonable time frame remain critical.

Regulatory non-compliances at four manufacturing facilities – The company is yet to resolve the warning letters issued by the USFDA to its Goa, Pithampur (Unit-II) and Mandideep plants. Lupin has received regulatory observations for its Somerset plant, which has been classified as OAI by the USFDA. These facilities together account for more than 60% of Lupin's pending ANDAs with the USFDA. The timely resolution of these warning letters and observations is critical and remains a key rating sensitivity. Lupin's management hopes to resolve these warning letters by H1 FY2021.

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

Lupin's liquidity position is strong with marked by consolidated unencumbered cash and liquid investments of Rs. 4,575 crore as on September 30, 2019. The company has maintained its track record of generating strong operating cash flows, driven by its healthy business profile. The liquidity is supported by Lupin's unutilised fund-based bank facilities of Rs. 1,314 crore as on September 30, 2019.

Rating sensitivities

Positive triggers – Not applicable

Negative triggers – Negative pressure on the ratings could emerge if there is weakening in the company's profitability, leading to an adverse impact on its credit profile. Weakening of the liquidity position due to aggressive capital expenditure or increased working capital intensity of operations will be a negative factor. 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 a negative trigger. Large debt-funded inorganic investments by the company or any adverse outcome of the ongoing investigations 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 rating methodology Methodology for Pharmaceutical Industry
Parent/Group Support	Not applicable
Consolidation / Standalone	For arriving at the rating, ICRA has considered the consolidated financials of Lupin. As on March 31, 2019, the company had 31 subsidiaries and one joint venture, that are enlisted in Annexure-2

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 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, Lupin Chemicals was merged with Lupin Laboratories Limited, following which the merged entity was renamed 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.

As per the company, Lupin is the eighth largest generics pharmaceutical company in the world by revenues (June 30, 2019). It is the third largest pharmaceutical player in US by prescriptions (IQVIA MAT, September 2019), the third largest Indian pharmaceutical company by global revenues (June 30, 2019), the sixth largest company in the IPM (IQVIA MAT, September 2019).

The company's business mix can be broadly divided into two segments - formulations (accounted for 91% of Lupin's consolidated revenues in H1 FY2020) and APIs (accounted for 8% of Lupin's consolidated revenues in H1 FY2020). The balance 1% was accounted for by licensing income received by Lupin for its new chemical entity licensed to Boehringer Ingelheim.

For the six-month period that ended on September 30, 2019, Lupin (consolidated, provisional) reported a profit after tax (PAT; before minority interest and share of profit from joint ventures/associates) of Rs.177.3 crore on an operating income (OI) of Rs. 8,778.0 crore, against PAT of Rs. 470.4 crore on an OI of Rs. 7,807.0 crore for the six-month period that ended on September 30, 2018.

Key financial indicators (audited, consolidated)

	FY2018	FY2019
Operating Income (Rs. crore)	15,806.6	16,885.0
PAT (Rs. crore)	3,159.2	3,068.6
OPBDIT/ OI (%)	20.0%	18.2%
RoCE (%)	4.0%	9.4%
Total Outside Liabilities/ TNW (times)	0.9	1.0
Total Debt/ OPBDIT (times)	2.3	2.8
Interest Coverage (times)	15.5	10.0
DSCR	12.3	3.4

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for last three years

S. No.	Instrument	Current Rating (FY2020)					Chronology of Rating History for the Past 3 Years			
		Type	Amount Rated (Rs. crore)	Amount outstanding (Rs. crore)		Date & Rating	Date & Rating in FY2019	Date & Rating in FY2018		Date & Rating in FY2017
					20-Nov-19	5-Apr-19	02-Aug-18	10-Nov-17	18-Oct-17	08-Aug-16
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 &	[ICRA]AAA (Stable)
4	Non-fund Based Facilities	Long-term	-	-		-	[ICRA]AAA &	[ICRA]AAA &	[ICRA]AAA &	[ICRA]AAA (Stable)

&-on rating 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 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	-	-	-	1,100.0	[ICRA]A1+
-	Non-fund Based Facilities	-	-	-	400.0	[ICRA]A1+

Source: Lupin Limited

Annexure-2: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation approach
Lupin Pharmaceuticals, Inc.	100.00%	Full Consolidation
Kyowa Pharmaceutical Industry Co., Limited	99.82%	Full Consolidation
Kyowa CritiCare Co., Limited	99.82%	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
Lupin Holdings 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
Nanomi B.V.	100.00%	Full Consolidation
Laboratorios Grin S.A. de C.V.	100.00%	Full Consolidation
Medquímica Indústria Farmacêutica LTDA	100.00%	Full Consolidation
Lupin Pharma LLC	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

Company Name	Ownership	Consolidation approach
Saker Merger Sub LLC (from April 7, 2017 and upto October 10,2017)	100.00%	Full Consolidation
Symbiomix Therapeutics, LLC (w.e.f. October 10, 2017)	100.00%	Full Consolidation
Lupin IP Ventures Inc. (w.e.f. October 10, 2017)	100.00%	Full Consolidation
Joint Venture		
YL Biologics Limited	45.00%	Equity method

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