Lupin Limited

April 05, 2019

Summary of rating action

Instrument*	Previous Rated Amount(Rs. crore)	Current Rated Amount(Rs. crore)	Rating Action
Long-term Fund-based Limits	150.0	0.0	-
Long-term Non-fund Based Limits	40.0	0.0	-
Short-term Fund-based Limits	950.0	1,100.0	[ICRA]A1+& (on rating watch with developing implications); reaffirmed
Short-term Non-fund Based Limits	360.0	400.0	[ICRA]A1+& (on rating watch with developing implications); reaffirmed
Total	**1,500.0**	**1,500.0**	

**Instrument details are provided in Annexure-1*

Rationale

The continuation of the rating watch with developing implications follows the pending resolution of warning letters issued by the US Food and Drug Administration (USFDA) to Lupin Limited's Goa and Pithampur (Unit-II, Madhya Pradesh) formulations manufacturing facilities. The rating watch is also on account of the regulatory observations received for two of the company's plants - one in Mandideep (Madhya Pradesh) and the other in Somerset (New Jersey, US) - which have been classified as Official Action Indicated (OAI) by the USFDA. These facilities together account for more than 60% of Lupin's pending abbreviated new drug applications (ANDAs) with the USFDA. The timely resolution of these warning letters and observations is critical and remains a key rating sensitivity.

The rating derives 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 fifth[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 also has a well-established presence in the 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 December 31, 2018, Lupin had 154 ANDAs pending approval, including 41 first-to-files (FTFs), of which 15 are exclusive opportunities. The rating also factors in Lupin's robust liquidity position, as evinced by its sizeable cash and bank balances and liquid investments of Rs. 2,732 crore and undrawn bank limits of Rs. 1,350 crore (as of September 30, 2018).

ICRA notes the moderation in the company's financial profile in FY2018 and 9M FY2019 due to the pressure on profitability on account of increased competition for key molecules and price erosion in the base business in the US and

[1] *Source: Quintiles September 2018, company presentation*

[2] *Source: Quintiles IMS MAT December 2018, company presentation*

Japan. Lupin witnessed YoY de-growth of 9% in revenues in FY2018, with 29% de-growth in revenues in the US market due to increased competition for its two key molecules, gFortamet and gGlumetza. Moreover, the company faced pricing pressure for other unbranded generics (in line with the industry) in the US on account of customer consolidation and increased competitive intensity, given the faster pace of ANDA approvals. The ramp-up of the portfolio acquired from Gavis Pharmaceuticals LLC was also below expectations. As a result, the company took an impairment charge of $227 million (~Rs. 1,464 crore; acquisition cost of $892 million incurred in March 2016) in Q4 FY2018. Lupin also had limited launches of complex molecules owing to the pending resolution of the warning letters for its Goa and Pithampur plants. The revenue growth in the domestic market also remained subdued at 8% YoY in FY2018 following the transition issues with respect to the implementation of the Goods and Services Tax (GST) and the resultant channel de-stocking, though Lupin continued to outperform the industry. Lupin's operating profit margin (OPM) thus moderated to 20.8% in FY2018 from 27.2% in FY2017.

The revenue growth remained flat in 9M FY2019 on account of a 12% YoY de-growth in revenues from US formulations sales. However, the company continued to report healthy double-digit revenue growth in the domestic formulations segment led by strong growth in chronic therapies. While the pricing erosion in the base business in the US, on account of channel consolidation, eased to single digits (vis-à-vis mid-to-high teens erosion in FY2017 and FY2018), Lupin's revenues remained impacted as one of its key branded molecules, Methergine, witnessed genericisation. Moreover, two other molecules (gGlumetza and gFortamet) continued to face competition. Lupin also launched its specialty product, Solosec, in the US in Q2 FY2019, which entailed high marketing and promotional expenses (~$12-13 million per quarter in 9M FY2019 against revenues of only $3 million per quarter).

The company has also been facing pricing pressure in the Japanese market, its third largest market, owing to annual price cuts announced by the government (against biennial price cuts earlier), not only for the unbranded segment but also for long-listed products. All these factors led to a further decline in Lupin's OPM to 16% in 9M FY2019. This also led to a moderation in its financial profile, as evinced by the softening of the coverage indicators, with net debt/OPBDITA of 2.8x and NCA/net debt (net cash accruals as a percentage of net debt) of 25% as of September 30, 2018. The net profit margin in 9M FY2019 was also impacted by a provision of EUR 42.8 million (Rs. 342.2 crore) in Q3 FY2019 pertaining to the fine imposed by the General Court of the European Union (EU) in the perindopril litigation, which has been appealed by the company in the higher Court.

Lupin, however, launched two key limited competition products in Q4 FY2019, gRanexa (for which it has 90 days exclusivity) and Levothyroxine, and proposes to launch some complex products (including complex generics and biosimilars) in FY2020 as well, which are expected to adequately support revenue growth and improve profitability over the medium term. The company also proposes to commercialise its first biosimilar, etanercept, in Japan in Q1 FY2020 (in partnership with Nichiko) and in the EU in Q2 FY2020 (in partnership with Mylan). Lupin's ability to maintain a healthy product portfolio in the 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. This apart, Lupin's ability to maintain the revenue traction in the domestic market and improve the revenue run rate in Japan would be important. 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

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 32% of its total sales in 9M

FY2019. Lupin has a well-established presence in the US generics market and ranks third, in terms of generic sales, in the US. It is the fifth largest player in the domestic formulations segment, which contributed 30% to its total sales in 9M FY2019. 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 ~9% to total consolidated revenues in 9M FY2019.

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 December 31, 2018, Lupin had 154 ANDAs pending approval including 41 FTFs, of which 15 are exclusive opportunities. In FY2019, the company launched its key specialty product, Solosec, in the women's heath space, which has been witnessing a healthy ramp up in prescriptions. The company launched limited competition products including gRanexa (for which it has 90 days exclusivity) and Levothyroxine in Q4 FY2019 and has an interesting line-up of limited competition products planned for FY2020 and FY2021, including Albuterol MDI, among others. Lupin also proposes to commercialise its first biosimilar, etanercept, in Japan in Q1 FY2020 (in partnership with Nichiko) and in the EU in Q2 FY2020 (in partnership with Mylan).

Domestic formulations business has continuously outperformed IPM growth – Lupin reported 13.5% YoY growth in its domestic formulations sales in 9M FY2019. The domestic segment continues to outperform the IPM, with the company registering revenue growth of 14.5% in H1 FY2019 (vis-à-vis industry growth of 12.1%) and 12% in Q3 FY2019 (vis-à-vis industry growth of 10.2%). The chronic therapies accounted for 58% of Lupin's domestic formulations business and recorded a robust YoY growth of 13% (vis-à-vis 8% for the market) in FY2018.

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. Lupin 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 has been strong with an unencumbered cash and bank balance and liquid investments of Rs. 2,732 crore as on September 30, 2018. It also had unutilised credit limits of Rs. 1,350 crore as on September 30, 2018.

Credit challenges

Profitability pressure in key US and Japan markets, thereby leading to moderation in financial profile – Lupin has been witnessing headwinds in its key market, the US, due to price erosion in its base generics business on account of channel consolidation in the US and increased competitive intensity. Profitability was also impacted in FY2018 and 9M FY2019 by increased competition for its key molecules, including gGlumetza, gFortamet and Methergine. The company has also been facing 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 to 20.8% in FY2018 and further to 16.0% in 9M FY2019, with a moderation in its return on capital employed (RoCE) to 4.8% in FY2018. This also led to a moderation in the financial profile, as evinced by the softening of the coverage indicators, with net debt/OPBDITA of 2.8x and NCA/net debt of 25% as of September 30, 2018. The company, however, launched two key limited competition products in Q4 FY2019 and proposes to launch some complex products (including complex generics and biosimilars) in FY2020 as well, which are expected to adequately support the revenue growth and improve profitability over the medium term.

Regulatory non-compliances at four manufacturing facilities – The company is yet to resolve the warning letters issued by the USFDA to its Goa and Pithampur (Unit-II) plants. Lupin has also received regulatory observations for two of its plants (Mandideep-Madhya Pradesh and Somerset), which have 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. The Goa and Pithampur units were re-inspected by the USFDA in January 2019, following which they received 483s with two and six observations (non-repeat), respectively. Lupin's management hopes to resolve these warning letters by Q2 FY2020.

Liquidity position

Lupin's liquidity position is strong with an unencumbered cash and bank balance and liquid investments of Rs. 2,732 crore as on September 30, 2018. The company has maintained its track record of generating strong operating cash flows, driven by its healthy business profile. However, even as the cash flow generation remains strong, Lupin has continued to fund a part of its requirements through external borrowings. Nonetheless, the liquidity position remains robust. The liquidity is also supported by Lupin's unutilised fund-based bank facilities of Rs. 1,350 crore as on September 30, 2018.

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 rating, ICRA has considered the consolidated financials of Lupin. As on March 31, 2018, the company had 33 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 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 market capitalisation (December 28, 2018) and revenues (September 30, 2018). It is the third largest pharmaceutical player in the US by prescriptions (IQVIA MAT, December 2018), the third largest Indian pharmaceutical company by global revenues (September 30, 2018), the sixth largest generic pharmaceutical player in Japan, and the fifth largest company in the IPM (IQVIA MAT, December 2018).

The company's business mix can be broadly divided into two segments - formulations (accounted for 90% of Lupin's consolidated revenues in 9M FY2019) and APIs (accounted for 9% of Lupin's consolidated revenues in 9M FY2019). The balance 1% was accounted for by licensing income received by Lupin for its new chemical entity licensed to AbbVie Inc. Lupin has a well-diversified geographical presence, with sales to advanced markets (US, Europe and Japan) accounting for ~54% of its total formulations sales in FY2018.

For the nine-month period ended December 31, 2018, Lupin (consolidated, provisional) reported a profit after tax (PAT; before minority interest and share of profit from joint ventures/associates) of Rs. 316.8 crore on an operating income (OI) of Rs. 12,311.9 crore. For the 12 months ended March 31, 2018, Lupin (consolidated) reported a PAT of Rs. 254.8 crore on an OI of Rs. 15,796.6 crore against a PAT of Rs. 2,554.4 crore on an OI of Rs. 17,367.4 crore for the 12 months ended March 31, 2017.

Key financial indicators (audited, consolidated)

	FY2017	FY2018
Operating Income (Rs. crore)	17,367.4	15,796.6
PAT (Rs. crore)	2,554.4	254.8
OPBDIT/ OI (%)	27.2%	20.8%
RoCE (%)	22.8%	4.8%
Total Debt/ TNW (times)	0.6	0.5
Total Debt/ OPBDIT (times)	1.7	2.2
Interest Coverage (times)	13.0	9.5

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
					April 2019	August 2018	November 2017	October 2017	August 2016
1	Fund-based Facilities	Short term	1,100.0	-	[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+
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+ &

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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
Gavis Pharmaceuticals, LLC	100.00%	Full Consolidation
Lupin Research Inc.	100.00%	Full Consolidation
Lupin Ukraine LLC	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
Saker Merger Sub LLC (from April 7, 2017 and up to October 10, 2017)	100.00%	Full Consolidation

Company Name	Ownership	Consolidation approach
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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