Dr. Reddy's Laboratories Ltd.

December 14, 2018

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term, Fund-based / Non-fund Based Limits	100.0	100.0	[ICRA]AA+ (Stable); re-affirmed
Short-term, Fund-based / Non-fund Based Limits	300.0	300.0	[ICRA]A1+; re-affirmed
Total	**400.0**	**400.0**	

*Instrument details are provided in Annexure-1

Rationale

The ratings derive comfort from Dr. Reddy's Laboratories Ltd.'s (DRL's) geographically diversified revenue mix, integrated presence across the value chain, healthy product pipeline and robust financial profile as evinced by its healthy debt coverage indicators. The ratings also factor in the company's increasing focus on limited competition niche products, injectables and biosimilars, which are expected to provide fillip to its revenues in the medium term given its strong research and development (R&D) capabilities. As on September 30, 2018, DRL had 110 abbreviated new drug applications (ANDAs) and three new drug applications (NDAs) pending approval from the US Food and Drug Administration (USFDA). The ratings also factor in the strong liquidity position of the company, supported by its sizeable cash and bank balances and liquid investments and undrawn working capital limits.

DRL witnessed a marginal 1% YoY de-growth in sales and 100 bps decline in operating profit margin (OPM) to 16.5% in FY2018. This was due to the continued price erosion in its key products such as decitabine, azacitidine, valgancyclovir, among others, (on account of channel consolidation in the US and increased competitive intensity) as well as supply constraints following regulatory issues at three of its manufacturing sites. —DRL's active pharmaceutical ingredients (API) manufacturing facilities at Mriyalguda (Telangana) and Srikakulum (Andhra Pradesh) and oncology formulations manufacturing facility at Duvvada (Vishakhapatnam, Andhra Pradesh) were under warning letters and 483 observations issued by the USFDA. While the company received successful Establishment Inspection report (EIR) for its facility at Mriyalguda in June 2017, it is yet to resolve the regulatory issues at the other two facilities. In addition, the revenue growth in the domestic formulations market was also impacted in FY2018 due to the goods and services tax (GST) transitional issues and under-performance of DRL (with respect to the industry) in the therapeutic areas of cardiovascular and anti-diabetes. Sales in the European market were also impacted in FY2018 due to the non-renewal of the Good Manufacturing Compliance Certificate in August 2017, which was later restored in January 2018. Above factors also led to moderation in the return indicators in FY2018.

The revenue growth rate has, however, improved in H1 FY2019, with a YoY growth of 10%. The price erosion in the US market has continued in H1 FY2019 as well, though as per the management, the same has now reduced to single digit vis-a-vis the mid to high teens decline witnessed in FY2018. Furthermore, while the company did not have any major limited competition product launch in FY2018, it has proposed three major product launches for FY2019 and FY2020, including gSuboxone, gNuvaring and gCopaxone, besides other product launches. Of these, the company made an at-risk launch of gSuboxone in June 2018; however, it had to stop the supplies post the imposition of the injunction by the innovator, Indivor. The company subsequently won the appeal in October 2018, but is yet to resume supplies of

gSuboxone. DRL is yet to receive the USFDA approval for the other two products, though the management is optimistic on the product launches in CY2019. DRL's revenue growth rate in the domestic formulations market has also improved in H1 FY2019 driven by new product launches as well as improvement in performance of the base business. Sales in European market, however, witnessed a YoY decline of 13% in H1 FY2019 due to price erosion in some of its key molecules. The company has embarked upon a cost rationalisation initiative since FY2018. Coupled with pick up in revenues, this has resulted in an improvement in its OPM to 20.2% in H1 FY2019, as against 14.4% in H1 FY2018.

DRL's ability to maintain a healthy product portfolio in US markets as well as timely resolution of the regulatory issues at its manufacturing facilities are critical for the revenue growth of the company and are the key rating sensitivities. This apart, ability of the company to maintain the revenue traction in the domestic market and improve the revenue run rate in the European market would be important determinants of the revenue growth. Large inorganic investments by the company would remain an event risk, and the impact of such investments on the company's business and credit profile would be monitored on a case by case basis.

Outlook: Stable

ICRA expects DRL to continue to maintain its heathy credit profile aided by strong cash accruals supported by improvement in revenue run-rate across major geographies as well as cost optimisation measures initiated by the company. The outlook may be revised to Positive if there is substantial growth in revenues and profitability of the company, leading to improvement in the return indicators and further strengthening of its financial risk profile. The outlook may be revised to Negative if cash accruals are lower than expected, or if any major capital expenditure, or stretch in the working capital cycle, weakens liquidity.

Key rating drivers

Credit strengths

Well diversified geographic mix, with a strong presence in key generic markets globally – DRL has a presence in both emerging and developed generics markets, with the US and Europe together contributing ~48% to its total sales in FY2018.

Integrated presence across the value chain – DRL has a strong and well-diversified business model supported by generic business (with the US being the key market), branded formulations business (in India and regulated markets), and backward integration in APIs. More of 60% of the global generics segment sales are from its vertically integrated APIs.

Strong R&D capabilities supporting development of a strong generic product pipeline (including first-to-file products, complex technology products and biosimilars) in developed markets – DRL has been investing significantly in R&D (12.9% of its operating income in FY2018), in line with its strategy to expand its focus on complex formulations, differentiated formulations and biosimilar compounds. DRL is one of the few Indian companies to have forayed into new drug discovery and development (NDDD) and new chemical entity (NCE) research, with a focus on therapies like dermatology, anti-inflammatory and anti-infectives as well as biosimilars.

Pipeline of limited competition products or complex generics for the US generic market indicates good opportunity if the issues related to warning letters are timely resolved – The company launched 15 and eight products in the US in FY2018 and H1 FY2019, respectively, and has several niche opportunities in the pipeline, including those acquired from Teva Pharmaceuticals in FY2016. As on September 30, 2018, DRL had 110 ANDAs and three NDAs pending approval from the USFDA. Near-term US revenue build up hinges on the resumption of sales of gSuboxone and timely approval for gCopaxone and gNuvaring. Besides, timely resolution of the regulatory issues would be critical to ensure further approvals and smooth launch of products.

Healthy financial profile and robust debt-coverage indicators – DRL's total consolidated net debt as on September 30, 2018 was Rs. 3.468.5 crore, resulting in comfortable (net) gearing of 0.3x. The coverage indicators, although moderated over the last two years, stand comfortable as reflected by OPBITDA/Interest of 37.9 times and NCA/Total Debt of 36% for H1 FY2019.

Credit challenges

Continued price erosion in the key US market on account of customer consolidation and increased competitive intensity – DRL has been witnessing headwinds in its key US market due to the price erosion in its key products such as decitabine, azacitidine, valgancyclovir, among others, on account of channel consolidation in the US and increased competitive intensity. Consequently, its OPM declined to 16.5% in FY2018. The price erosion has continued in H1 FY2019 as well, though as per the management, the same has now reduced to single digits vis-a-vis the mid to high teens decline witnessed in FY2018. Increased focus on cost containment by the governments in various regulated markets may also limit profitability of generic players.

Warning letters issued to the Srikakulam API facility and Duvvada formulations facility – During FY2018, DRL had faced supply constraints following regulatory issues at three of its manufacturing sites—API manufacturing facilities at Mriyalguda and Srikakulum and oncology formulations manufacturing facility at Duvvada—in light of the warning letters and 483 observations issued by the USFDA. While the company received successful EIR for its facility at Mriyalguda in June 2017, it is yet to resolve the regulatory issues at the other two facilities. Timely resolution of these issues would be critical to ensure further approvals and smooth launch of products.

On-going intellectual property litigation for one of its key products, gSuboxone; delays in resolution of the same/ adverse outcome can impact its revenue growth prospects over the near to medium term –In June 2018, DRL made an at-risk launch of gSuboxone, one of its key proposed product launches for FY2019. The company, however, had to stop the supplies post the imposition of the injunction by the innovator, Indivor. The company subsequently won the appeal in October 2018; however, it is yet to resume supplies of gSuboxone. Resumption of sales of gSuboxone remains critical for the ramp up of revenues of DRL.

Liquidity Position:

The liquidity position of DRL is strong with unencumbered cash and bank balance and liquid investments amounting to Rs. 2,351.7 crore as on March 31, 2018 and Rs. 3,468.5 crore as on September 30, 2018, though it has reduced from Rs. 4,194,1 crore as on March 31, 2016, mainly due to its utilisation for share buyback amounting to ~Rs. 1,569 crore during FY2017. The company also had unutilised credit limits of Rs. 2,404.6 crore (PY: Rs 2,115.6 crore) as of March 31, 2018. The cash flow generation of the company is also expected to remain strong in FY2019 supported by improvement in revenue growth across major geographies as well as cost optimisation measures initiated by the company

Analytical approach:

Analytical Approach	Comments
Applicable Rating Methodologies	Corporate Credit Rating Methodology Methodology for Pharmaceutical Industry
Parent / Group Support	Not Applicable.
Consolidation / Standalone	For arriving at the ratings, ICRA has considered the consolidated financials DRL. As on March 31, 2018, the company had 51 subsidiaries and two joint ventures, that are enlisted in Annexure-2.

About the company:

DRL was incorporated by its promoter and founder chairman, the Late Dr. K. Anji Reddy, as a private limited company on February 24, 1984. The company was subsequently converted to a public limited company on December 6, 1985 and listed on the Bombay Stock Exchange (BSE) and the National Stock Exchange (NSE) in August 1986 as well as on the New York Stock Exchange (NYSE) on April 11, 2001. As on September 30, 2018, the promoters and promoter Group held 26.77% stake in the company.

DRL offers a portfolio of products and services including pharmaceutical generics, APIs, custom pharmaceutical services, biosimilars and differentiated formulations. It has three divisions—global generics (accounted for 80% of the revenues of the company in FY2018), pharmaceutical services and active ingredients (accounted for 16% of the revenues of the company in FY2018) and proprietary products (accounted for 4% of the revenues of the company in FY2018). The major therapeutic areas of focus for the company include gastro-intestinal, cardiovascular, diabetology, oncology, pain management and dermatology, with the USA, India, Russia and Commonwealth of Independent States (CIS) countries being the major markets.

The company has nine API manufacturing facilities, of which seven are USFDA approved (six in India and one in Mexico) and 12 formulations manufacturing facilities, of which five are USFDA approved (three in India and one in the US and the UK each). Of these, the company has received warning letters from the USFDA for two facilities (one API facility at Srikakulam (Andhra Pradesh) and one oncology formulations facility at Duvvada (Andhra Pradesh) and 483 observations for two API facilities (Hyderabad plant-1 and 3). In addition, the company has one biologics facility in India and several technology development and R&D centres in India and across the globe. DRL has a nine-member Board, comprising two promoter directors and seven independent directors, each an eminent personality in the field of finance, strategic consulting, science and economics.

For the six-month period ended September 30, 2018, DRL reported a profit after tax (PAT) of Rs. 975.2 crore on an operating income (OI) of Rs. 7,554.0 crore. For the 12-month period ended March 31, 2018, , DRL reported a PAT of Rs. 912.4 crore on an OI of Rs. 14,281.0 crore, as against a PAT of Rs. 1,257.2 crore on an OI of Rs. 14,196.1 crore for the 12-month period ended March 31, 2017.

Key financial indicators (audited, consolidated)

	FY 2017	FY 2018
Operating Income (Rs. crore)	14,196.1	14,281.0
PAT (Rs. crore)	912.4	1,257.2
OPBDIT/ OI (%)	17.5%	16.5%
RoCE (%)	11.3%	10.2%
Total Debt/ TNW (times)	0.4	0.4
Total Debt/ OPBDIT (times)	2.0	2.2
Interest coverage (times)	35.2	29.8

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for last three years:

	Instrument	Current Rating (FY2019)				Chronology of Rating History for the Past 3 years		
		Type	Amount Rated (Rs. crore)	Amount Outstanding (Rs Crore)	Date &Rating December 2018	Date &Rating FY2018 September2017	Date & Rating in FY2016 March 2016	Date & Rating in FY2016 January 2015
1	Fund-based / Non-fund Based Limits	Long-term	100.0	-	[ICRA]AA+ (Stable)	[ICRA]AA+ (Stable)	-	-
2	Fund-based / Non-fund Based Limits	Short-term	300.0	-	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+	[ICRA]A1+

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 Name	Date of Issuance / Sanction	Coupon Rate	Maturity Date	Amount Rated (Rs. crore)	Current Rating and Outlook
-	Fund-based / Non-fund Based Limits	NA	NA	NA	100.0	[ICRA]AA+ (Stable)
-	Fund-based / Non-fund Based Limits	NA	NA	NA	300.0	[ICRA]A1+

Source: Dr. Reddy's Laboratories Ltd.

Annexure-2: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation Approach
Aurigene Discovery Technologies(Malaysia) Sdn. Bhd.	100.00%	Full Consolidation
Aurigene Discovery Technologies, Inc.	100.00%	Full Consolidation
Aurigene Discovery Technologies Limited	100.00%	Full Consolidation
beta Institut gemeinnützige GmbH	100.00%	Full Consolidation
betapharm Arzneimittel GmbH	100.00%	Full Consolidation
Cheminor Investments Limited	100.00%	Full Consolidation
Chirotech Technology Limited	100.00%	Full Consolidation
DRL Impex Limited	100.00%	Full Consolidation
Dr. Reddy's Bio-Sciences Limited	100.00%	Full Consolidation
Dr. Reddy's Farmaceutica Do Brasil Ltda.	100.00%	Full Consolidation
Dr. Reddy's Laboratories (Australia)Pty. Limited	100.00%	Full Consolidation
Dr. Reddy's Laboratories Canada, Inc.	100.00%	Full Consolidation
Dr. Reddy's Laboratories Chile SPA.	100.00%	Full Consolidation
Dr. Reddy's Laboratories (EU) Limited	100.00%	Full Consolidation
Dr. Reddy's Laboratories, Inc	100.00%	Full Consolidation
Dr. Reddy's Laboratories International SA	100.00%	Full Consolidation
Dr. Reddy's Laboratories Japan KK	100.00%	Full Consolidation
Dr Reddy's Laboratories Kazakhstan LLP	100.00%	Full Consolidation
Dr. Reddy's Laboratories LLC	100.00%	Full Consolidation
Dr. Reddy's Laboratories Louisiana, LLC	100.00%	Full Consolidation
Dr. Reddy's Laboratories Malaysia Sdn. Bhd.	100.00%	Full Consolidation
Dr. Reddy's Laboratories New York, Inc.	100.00%	Full Consolidation
Dr. Reddy's Laboratories (Proprietary) Limited	100.00%	Full Consolidation
Dr. Reddy's Laboratories Romania S.R.L.	100.00%	Full Consolidation
Dr. Reddy's Laboratories SA	100.00%	Full Consolidation
Dr. Reddy's Laboratories S.A.S.	100.00%	Full Consolidation
Dr. Reddy's Laboratories Taiwan Limited	100.00%	Full Consolidation
Dr. Reddy's Laboratories Tennessee,LLC	100.00%	Full Consolidation
Dr. Reddy's Laboratories (UK) Limited	100.00%	Full Consolidation
Dr. Reddy's Research and Development B.V.	100.00%	Full Consolidation
Dr. Reddys Singapore Pte. Limited.	100.00%	Full Consolidation
Dr. Reddy's S.R.L.	100.00%	Full Consolidation
Dr. Reddy's New Zealand Limited	100.00%	Full Consolidation
Dr. Reddy's (WUXI) Pharmaceutical Co.Limited	100.00%	Full Consolidation
Dr. Reddy's Venezuela, C.A.	100.00%	Full Consolidation
Eurobridge Consulting B.V.	100.00%	Full Consolidation

Company Name	Ownership	Consolidation Approach
Idea2Enterprises (India) Private Limited	100.00%	Full Consolidation
Imperial Credit Private Limited	100.00%	Full Consolidation
Industrias Quimicas Falcon de Mexico,S.A. de CV	100.00%	Full Consolidation
Kunshan Rotam Reddy Pharmaceutical Company Limited	51.33%	Equity Method
Lacock Holdings Limited	100.00%	Full Consolidation
OOO Dr. Reddy's Laboratories Limited	100.00%	Full Consolidation
OOO DRS LLC	100.00%	Full Consolidation
Promius Pharma, LLC	100.00%	Full Consolidation
Reddy Antilles N.V.	100.00%	Full Consolidation
Reddy Holding GmbH	100.00%	Full Consolidation
Reddy Netherlands B.V.	100.00%	Full Consolidation
Reddy Pharma Iberia S.A.U.	100.00%	Full Consolidation
Reddy Pharma Italia S.R.L.	100.00%	Full Consolidation
Reddy Pharma S.A.S.	100.00%	Full Consolidation
Regkinetics Services Limited	100.00%	Full Consolidation
Joint Ventures		
DRANU LLC	50.00%	Equity Method
DRES Energy Private Limited	26.00%	Equity Method

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About ICRA Limited:

ICRA Limited was set up in 1991 by leading financial/investment institutions, commercial banks and financial services companies as an independent and professional investment Information and Credit Rating Agency.

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