

Alembic Pharmaceuticals Limited

June 19, 2023

Facilities/Instruments	Amount (₹ crore)	Rating ¹	Rating Action
Commercial paper	750.00	CARE A1+	Reaffirmed

Details of instruments/facilities in Annexure-1.

Rationale and key rating drivers

The rating assigned to the commercial paper (CP) issue of Alembic Pharmaceuticals Limited (APL) continues to derive strength from its experienced and qualified management in the pharmaceutical industry, its long track record and established presence in the domestic formulation market with strong formulation portfolio, presence in the major regulated markets and its diversified revenue profile with vertically-integrated operations. The rating further derives comfort from its healthy financial risk profile marked by large net worth base, low debt level and strong liquidity.

The above rating strengths are, however, partially off-set by significant moderation in operating profitability margin due to pricing pressure in the US generic market, and saleability risk and overhead cost associated with the recently-commissioned new facilities which shall restrict the profitability and return ratio (return of capital employed; ROCE) in the near term. The rating is further constrained on account of its exposure to the inherent regulatory risk associated with the pharmaceutical industry coupled with intense competition and resultant pricing pressure in both domestic and export markets. CARE Ratings Limited (CARE Ratings) also take note of reduction in net worth base during FY23 due to sizable impairment of ₹1,150 crore.

Rating sensitivities: Factors likely to lead to rating actions

Negative factors

- Significantly larger-than-envisaged capex or acquisition adversely affecting its free cash flows and debt coverage indicators
- Increase in the overall gearing ratio greater than 0.5x on a sustained basis
- Decline in PBILDT margin below 15% along with significant adverse impact on its ROCE on a sustained basis on account of lower-than-envisaged benefits from recently commissioned facilities

Analytical approach: Consolidated. CARE Ratings has considered the consolidated financials of APL because of operational and financial linkages with its subsidiaries/joint ventures (JVs)/associates. The list of entities consolidated in APL as on March 31, 2023, are mentioned in **Annexure 6**.

Key strengths

Qualified and experienced management: Since its incorporation in the year 1907 (earlier known as Alembic Chemical Works) by B.D. Amin, the Amin family has driven the operations of APL. Chirayu Amin (Chairman) is a third-generation entrepreneur and has more than three decades of experience in the Indian pharmaceutical industry (IPI). Pranav Amin (MD) and Shaunak Amin (MD), sons of Chirayu Amin, also possesses experience of more than a decade in the pharmaceutical industry. Furthermore, APL has well-qualified and experienced second-tier management with well-defined organisational structure and strong management information system.

Diversified and vertically-integrated operations: APL's business is mainly divided into three broad business segments, i.e., (i) branded formulations (sales of formulations in the domestic market); (ii) international generic formulations (sale of formulations in the export markets); and (iii) active pharmaceutical ingredients (API; catering to both domestic and export markets). These segments contributed around 36%, 43% and 21% of its consolidated total operating income (TOI), respectively, during FY23 indicating fairly-diversified revenue stream. APL's revenue profile is also geographically well diversified with presence in the major regulated and semi-regulated markets; albeit there is greater focus on the US (generic formulation sales in US contributed around 36% of its TOI in FY23). During FY23, the revenue from its US generic business de-grew by 23% on y-o-y basis primarily on account of increased competition and subsequently higher price erosion. Domestic branded formulation business grew by 7% on a relatively higher base of FY22 while API business grew healthy by 24% in FY23 on a y-o-y basis. With availability of large capacities and strong domestic demand for API, the revenue contribution from API business is likely to grow further in the coming years. CARE Ratings expects API business to grow at around 15% annually over medium term.

APL's top 10 brands in the domestic market constituted around 42% of its branded formulation sales during FY23 (47% during FY22). Furthermore, its top 10 generic formulations in the US market constituted around 27% of its US generic formulation sales, which indicates fair diversification. CARE Ratings expects APL to continue to benefit by its diversified product portfolio both in domestic and regulated market. Furthermore, with expectation of new product launches particularly in the US market, the revenue contribution from top 10 generic formulations is likely to reduce in future.

¹Complete definition of the ratings assigned are available at <u>www.careedge.in</u> and other CARE Ratings Ltd.'s publications



APL has vertically-integrated operations as it captively meets its API requirement for its key final products apart from selling API to the customers. APL's ability to manufacture API for its key formulations partially protects it from the supply uncertainties and volatility in the prices of API.

Long track record and established position in the domestic formulation market: APL has an operational track record of over a century in the Indian pharmaceutical industry and is among the top 25 pharma players in the domestic formulation market. APL ranked 21^{st} with market share of 1.5% in the domestic pharmaceutical market (Source: Company). APL has a portfolio of 185 domestic formulation brands out of which three formulation brands are among the top 300 domestic formulation brands in India and has over 1,000 products (SKUs). APL has a field force of over 5,000 executives reaching over 2,00,000 medical practitioners across India. The medical representative (MR) productivity stood at around ₹4 lakh per MR per month during FY23, which increased from ₹3.58 lakh per MR per month in FY22.

APL earned nearly 69% of its domestic revenue from top five therapeutic segments including Anti-infective (22% of its domestic revenue), Cardiology (13%), Gastrology (11%), Gynaecology (13%) and Cold & cough (11%).

Large presence in regulated markets backed by consistent R&D focus: Over the last 5-6 years, APL has gradually increased its presence in the overseas markets, where the majority of contribution is coming from the regulated markets like US. Till FY21, APL had demonstrated a strong operational performance in the US market led by increasing product approvals, new product launches, and several short-term supply opportunities in the Sartan group of formulation due to regulatory issues faced by its competitors. However, APL's US generic business started facing pricing pressure from FY22 resulting into lower sales realization and profitability. After witnessing a de-growth of 23% in US generic business in FY22 on a y-o-y basis, it witnessed de-growth of 6% in FY23. There has been consolidation of distributors in US where top three distributors account for more than 90% of the drug market in the US. With this, the pricing power of suppliers have reduced considerably. With majority of price erosion curbed, the company is expected to grow its US generic business through launches of new products coupled with expected increase in the market share of the existing products.

APL made sizable investments in its R&D capabilities (annual R&D spend of around 12% to 14% during the past three years ended FY23) to grow its presence in the regulated markets. However, the company has consciously decided to curtail its R&D budget considering the competition in certain products in US generics market. Furthermore, the company has decided to curtail its development projects of certain products where the patent expiry is towards FY29 and beyond. The reduction in R&D expenditure is not expected to have any material impact on the existing business and products under development for immediate period expiries. During FY23, the company has filed nearly 15 ANDAs leading to cumulative ANDA filling of 245 as on March 31, 2023. Furthermore, the company has received 19 ANDA approvals during FY23 leading to cumulative ANDA approvals of 179 as on March 31, 2023. APL had launched 15 products during FY23, and it envisages to launch nearly 20-25 products in the US market during FY24 and 10-12 products every year thereafter. CARE Ratings expects compounded annual growth rate of around 12% in TOI over FY23-FY26.

Despite decline in net worth base, the capital structure continued to remain comfortable: The company written-off/ undertook impairment $\gtrless1,150$ crore during FY23 related to pre-operative expenses recognized as part of the outstanding capital work-in-progress (CWIP) for three of its new manufacturing facilities. The company used the available general reserves for this impairment which has resulted in a sharp decline in net worth base during FY23. However, due to relatively low debt of $\gtrless722$ crore (Including Rs.86 crore of lease liability) as on March 31, 2023, the overall gearing ratio remained comfortable at below 0.2 time as on even date. APL's overall gearing is expected to remain below 0.20x in the medium term in the absence of any major debt-funded capex plan and gradual reduction in working capital borrowings.

APL's debt coverage indicators also remain comfortable marked by total debt/PBILDT of 0.85x and total debt/GCA of 0.92 years during FY23. The debt coverage indicators are expected to remain comfortable due to APL's healthy profitability and envisaged reduction in working capital borrowings in the near to medium term. CARE Ratings expects cash accruals to remain adequate to meet its envisaged capex and working capital requirement and there would not be any major reliance on external debt.

Stable growth prospects of Indian pharmaceuticals sector: The Indian pharmaceutical industry (IPI) comprises mainly of formulations, active pharmaceutical ingredients (API) and contract research and manufacturing services (CRAMS) segments. The outlook for IPI is envisaged to remain stable in the medium to long term backed by growth opportunity in terms of capitalising on major blockbuster drugs coming off-patent, paving the way for entry of generics, especially in the US market, and geographical diversification into emerging markets. In the domestic market, the growth in the formulations segment is expected to be led by rise in chronic diseases, increasing per capita income, government initiatives like new national health protection scheme and Ayushman Bharat programme, and improvement in the access to healthcare facilities along with growing penetration of health insurance.



Liquidity: Strong

The liquidity of the company is expected to remain strong in the absence of any scheduled repayment obligation over FY24-FY26. Furthermore, APL's liquidity indicator continued to remain strong marked by current ratio of 1.79 times as on March 31, 2023. APL's internal accruals are expected to remain adequate to meet its capex and working capital requirement. The utilization of its fund-based working capital limits (on a standalone basis) also remained at around 49% for the trailing 12 months ended April 2023. Furthermore, its un-utilized working capital limits provide additional liquidity cushion. This apart, its healthy net-worth base and comfortable leverage provide significant financial flexibility to APL.

Key weaknesses

Muted revenue growth along with moderation in profitability during FY23: Total operating income grew by around 5% during FY23 primarily supported by healthy growth in revenue from API segment followed by growth in domestic market while international generic business witnessed de-growth. The US generic business de-grew by 6% during FY23 over FY22 while ROW market registered a growth of around 10% during the period. Along-with muted revenue growth, APL's operating profitability (PBILDT) margin was adversely impacted during FY23 due to the higher-than-envisaged pricing pressure in the US market. APL's PBILDT margin [excluding non-recurring expenses related to the intangible assets of Aleor Dermaceuticals Limited (ADL)] stood moderate at 15% during FY23 as compared with 19% in FY22. APL took impairment of accumulated intangible assets under its subsidiary, ADL, consequent to change in accounting treatment for recognition of ADL's R&D expenses. Due to the aforesaid change in accounting treatment, there was a negative impact of ₹155 crore in the consolidated net profit for FY23 (FY22: ₹123 crore). Despite decline in the operating profit, the fall in net profit and cash accruals of the company was restricted due to substantial saving in tax outgo during FY23.

Commercialization of the newly set-up facilities; albeit gradual ramp-up expected which shall restrict its profitability and ROCE in near term: APL embarked on the capex programme targeted towards increasing its presence in the US market by offering more complex and specialty products. APL set-up three new manufacturing facilities targeted to cater the US market. *A*II the three new manufacturing facilities are now approved by the US Food and Drug Administration (USFDA). APL has started commercial operations from one of its new manufacturing facilities in H2FY23 while it started commercial production of another two facilities during the early part of FY24. Management expects a gradual ramp-up in production and sales from these facilities.

Going forward, upon commercialization of new manufacturing facilities, the overhead cost associated to these facilities shall be charged to P&L account from FY24. This may impact profitability and ROCE in near to medium term till the time the company achieves the optimum capacity utilization of these assets. CARE Ratings expects PBILDT margin to remain at around 15% in FY24-FY25 and it shall improve to around 18% in FY26 compared to the earlier envisaged level of 20-222%. ROCE to remain at around 14-16% in FY24-FY26.

Inherent regulatory risk in the domestic and international market: APL derived around 36% of its revenue during FY23 from domestic formulation business. Also, around 14-15% of its formulations feature in the National List of Essential Medicine (NLEM). Inclusion of any fresh formulations in NLEM and consequently in the Drug Prices Control Order (DPCO) may restrict the pricing flexibility for APL. It is also exposed to the regulatory changes in global markets (primarily US) as international generic business contributed nearly 43% to its revenue during FY23. Continuous efforts by the US government to bring down drug prices, intense competition in the US generic market and consolidation of the US pharmaceutical distributors, may pose vulnerability to its profitability. The pricing in generic formulations in the regulated market, especially the US is mainly driven by the dynamics of demand and supply. Apart from this, the wholesale pharmacy market in the US is dominated by very few distributors. Moreover, any non-compliance with good manufacturing practice (GMP) and subsequent adverse action by USFDA may also pose threat to the revenue and profitability of the company. However, APL has establishment inspection report (EIR) in place for all its operational manufacturing facilities.



Environment, social, and governance (ESG) risks

Risk factors	Compliance and action by the company
Environmental	The company has Zero Liquid Discharge (ZLD) implemented facility. APL has taken various initiatives to reduce carbon emission as well for reduction in waste sent to landfilling site by sending waste to recycling & to cement industry to an extent. Company has also invested in renewable energy by installing windmills & solar panels.
Social	APL faces a high social risk related to the safety of the consumers. Further, APL is exposed to reputation risk related to the quality of the product/ services. However, there have not been any major instances of litigations and product recall in the past. APL continue to comply with the various labour laws, adequate safety for workers, ensuring customer privacy and fair marketing practices to achieve long-term sustainability. Company also launched various programs such as Swasthya Setu wherein a mobile health van with medical practitioners visits 25 villages, launched program "Suposhan" targeted to cater need of food for around 1700 Childrens across 15 villages, Blood transfusion center to curb thalassemia & had benefited 55 patients, & various other educational programs for Childrens.
Governance	APL has adequate governance structure, with majority of its board comprising independent directors, presence of investor grievance redressal mechanism, whistle-blower policy and extensive disclosures. APL has implemented human rights policy and prevention of sexual harassment policy.

Applicable criteria

Policy on default recognition Consolidation Financial Ratios – Non financial Sector Liquidity Analysis of Non-financial sector entities Short Term Instruments Manufacturing Companies Pharmaceutical Policy on Withdrawal of Ratings

About the company and industry

APL is engaged in the manufacturing and marketing of branded formulations (in the domestic market), generic formulation (in overseas market) and API/ bulk drug in domestic and overseas markets. With effect from April 1, 2010, the core pharmaceutical business of Alembic Limited (which was originally incorporated in 1907 as Alembic Chemical Works) was demerged into APL. APL caters to several therapeutic segments, which include anti-infective, gynaecology, cardiology, diabetes, dermatology and oncology, wherein the anti-infective segment contributes the most to its revenue in the domestic market. Furthermore, USA forms major share of APL's revenue in its export market. APL operates total nine manufacturing facilities at different locations in India (six formulation facilities and three API facilities).

Industry classification

Macro-Economic Indicator	Sector	Industry	Basic Industry
Healthcare	Healthcare	Pharmaceuticals & Biotechnology	Pharmaceuticals

Brief Financials – Consolidated (₹ crore)	FY22 (A)	FY23 (Ab.)
Total operating income	5,350	5,631
PBILDT	1,041	847
PAT	521	342
Overall gearing (times)	0.14	0.17
Interest coverage (times)	60.41	16.88

A: Audited, Ab.: Abridged; Note: 'the above results are latest financial results available'

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

Rating history for last three years: Please refer Annexure-2

Covenants of rated instrument / facility: Detailed explanation of covenants of the rated instruments/facilities is given in

Annexure-3

Complexity level of various instruments rated: Annexure-4

Lender details: Annexure-5



List of subsidiary consolidated: Annexure-6

Annexure-1: Details of instruments/facilities

Name of the Instrument	ISIN	Date of Issuance (DD-MM- YYYY)	Coupon Rate (%)	Maturity Date (DD- MM-YYYY)	Size of the Issue (₹ crore)	Rating Assigned along with Rating Outlook
Commercial Papers	INE901L14AK0	13-Apr-2023	7.40%	11-July-2023	100.00	CARE A1+
Commercial Papers	INE901L14AL8	11-May-2023	7.27%	08-Aug-2023	150.00	CARE A1+
Commercial Papers	INE901L14AM6	23-May-2023	7.26%	18-Aug-2023	100.00	CARE A1+
Commercial Papers	NA	-	-	-	400.00	CARE A1+

The company has availed CP of Rs.350.00 crore out of the total rated CP issue of Rs.750.00 crore as on May 26, 2023.

Annexure-2: Rating history for the last three years

Sr. No.		Current Ratings			Rating History			
	Name of the Instrument/Bank Facilities	Туре	Amount Outstanding (₹ crore)	Rating	Date(s) and Rating(s) assigned in 2023- 2024	Date(s) and Rating(s) assigned in 2022- 2023	Date(s) and Rating(s) assigned in 2021- 2022	Date(s) and Rating(s) assigned in 2020- 2021
1	Commercial Paper- (Standalone)	ST	750.00	CARE A1+	-	1)CARE A1+ (21-Jun- 22)	1)CARE A1+ (22-Jun- 21)	1)CARE A1+ (25-Jun- 20)

*Long term/Short term.

Annexure-3: Detailed explanation of covenants of the rated instruments/facilities: Not applicable

Annexure-4: Complexity level of the various instruments rated

Sr. No.	Name of the Instrument	Complexity Level
1	Commercial Paper- (Standalone)	Simple

Annexure-5: Lender details

To view the lender wise details of bank facilities please click here

Annexure-6: List of subsidiaries consolidated

Sr. No.	Name of the entities	Relationship	% Equity stake of APL as on Mar 31, 2023
1	Alembic Global Holding SA (AGH)	Subsidiary of APL	100%
2	Alembic Pharmaceuticals (AP) Inc.	Subsidiary of APL	100%
3	Alembic Pharmaceuticals SPA	Subsidiary of APL	100%
4	Alembic Pharmaceuticals Europe Limited	Step-down subsidiary	100%
5	Alembic Pharmaceuticals Canada Limited	Step-down subsidiary	100%
6	Alembic Pharmaceuticals Australia Pty Limited	Step-down subsidiary	100%
7	Alnova Pharmaceuticals SA	Step-down subsidiary	100%
8	Genius LLC	Step-down subsidiary	100%
9	Alembic Labs LLC	Step-down subsidiary	100%
10	Okner Realty LLC	Step-down subsidiary	100%
11	Incozen Therapeutics Pvt. Ltd.	Associate of APL	50%
12	Rhizen Pharmaceuticals SA (RPSA)	Associate of AGH	50%
13	Dahlia Therapeutics SA	Subsidiary of RPSA	50%
14	Rhizen Pharmaceuticals Inc.	Subsidiary of RPSA	50%



Note on the complexity levels of the rated instruments: CARE Ratings has classified instruments rated by it on the basis of complexity. Investors/market intermediaries/regulators or others are welcome to write to care@careedge.in for any clarifications.

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About us:

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