Alembic Pharmaceuticals Limited

June 21, 2022

Rating

Instruments	Amount (₹ crore)	Rating[1]	Rating Action
Commercial paper (CP) issue (Standalone)	750.00 **(₹ Seven hundred fifty crore only)**	**CARE A1+ (A One Plus)**	**Reaffirmed**

Details of Instrument in Annexure-1.

Detailed 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 pharmaceutical industry with strong formulation portfolio, growing export 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 growing scale of operations, healthy profitability, low leverage, comfortable debt coverage indicators and strong liquidity. CARE Ratings Limited (CARE Ratings) takes cognisance of the muted growth in the total operating income (TOI) along with moderation in the operating profitability (profit before interest, lease rentals, depreciation and taxation [PBILDT]) margin of APL during FY22 (A; refers to the period April 01 to March 31), which also remained lower-than-envisaged due to higher-than-anticipated price erosion in the United States of America (US) generic market.

The above rating strengths are, however, partially off-set by continued delay in the commencement of commercial operations of its various new projects; along with the salability risk associated with it. The delay in commencement also impacts the return indicators of the company due to large-size capital employed towards setting-up new capacities. 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 as well as export markets.

Rating sensitivities

Negative factors – Factors that could lead to negative rating action/downgrade:

- 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 the PBILDT margin below 15% along with significant adverse impact on its return on capital employed (ROCE) on a sustained basis most likely emanating from inordinate delay in commissioning its ongoing large-size capex and realising envisaged benefits therefrom.

Detailed description of the key rating drivers

Key rating strengths

Qualified and experienced management: Since its incorporation in the year 1907 (earlier known as Alembic Chemical Works) by Mr B.D. Amin, the Amin family has driven the operations of APL. Mr Chirayu Amin (Chairman) is a third-generation entrepreneur and has more than three decades of experience in the Indian pharmaceutical industry (IPI). Mr Pranav Amin (MD) and Mr Shaunak Amin (MD), sons of Mr Chirayu Amin, also possess 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, ie, (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%, 46% and 18% of its consolidated TOI, respectively, during FY22 indicating fairly diversified revenue stream. The revenue profile of APL is also geographically 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 31% of its TOI). APL's top 10 brands in the domestic market constituted around 47% of its branded formulation sales during FY22 (79% during FY21 and 51% during FY20). Furthermore, its top 10 generic formulations in the US market constituted around 35%-40% of its US generic formulation sales, which indicates fair diversification.

[1]Complete definition of the ratings assigned are available at www.careedge.in 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 IPI. APL's domestic formulation business grew by 29% on y-o-y basis during FY22 as against the y-o-y industry growth of 18%. APL has taken various steps like transitioning of its product portfolio, optimised supply chain and building up a strong marketing team over the period of last few years to strengthen its domestic business. Consequently, APL's domestic business growth outpaced industry average over the last two years. APL's domestic formulation sales is expected to grow at a higher rate compared to the industry average in the near to medium term.
APL has a portfolio of over 185 formulation brands out of which three formulation brands are among the top 300 domestic formulation brands in India (Source: Company). APL has a field force of over 5,500 executives reaching out to over 225,000 medical practitioners across India. The medical representative (MR) productivity stood at nearly 3.58 lakh per MR per month during FY22. APL earned nearly 71% of its domestic formulation revenue during FY22 from top five therapeutic segments comprising anti-infective, cardiology, gastroenterology, gynecology, and cold & cough.

Increasing presence in the regulated export markets backed by increasing R&D focus: APL's generic formulations sales (mostly in the regulated markets) grew at a compounded annual growth rate (CAGR) of around 19% during the last four years ended FY22. However, it de-grew by 17% on y-o-y basis during FY22, primarily on account of increased competition and higher price erosion in the US generic market. However, the company has witnessed some recovery in its US generic business in Q4FY22. During Q4FY22, APL's US generic revenue grew by 17% on y-o-y basis and 42% on q-o-q basis supported by increase in the market share of some of its existing products, easing of pricing pressure and one-off factors like channel stocking and one-time supply opportunity. APL's revenue from the rest of the world (ROW) largely remained stable in FY22 over FY21 despite the higher base of last year.
APL's strong operational performance in the regulated markets was on account of its continuous focus on Research and Development (R&D) resulting into increasing product approvals, new product launches, and capitalising upon several supply opportunities arising due to shortage of the Sartan group of formulations in the US market. APL made sizable investments in its R&D capabilities (annual R&D spend of around 12% to 14% during the past three years ended FY22) to grow its presence in the regulated markets. Its higher R&D outlay has helped to enlarge its product portfolio for the US market. Up to March 31, 2022, APL had filed 230 (212 as on March 31, 2021) abbreviated new drug applications (ANDA), out of which 160 (139) were approved and 105 (86) products were launched. APL expects to launch 15 to 20 new products in the US market during FY23 backed by strong product pipeline and ANDA filings.

Healthy operating profitability, albeit some moderation during FY22: APL's TOI largely remained stable at ₹5,350 crore during FY22 despite healthy revenue growth in domestic formulation business which was off-set by the de-growth in revenue from US generic business. Going forward, launches of new products coupled with expected increase in the market share of existing products is envisaged to help the company to off-set the likely mid-single digit price erosion in the US market. Furthermore, APL's domestic formulation business is expected to outpace the industry growth, which shall also support its overall revenue growth.
APL's operating profitability (PBILDT) margin was also adversely impacted during FY22 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 healthy at 19% during FY22 as compared with 28% in FY21. The higher profitability in FY21 was also due to some short-term opportunity, which arose in the US market pertaining to the Sartan group of formulations.
Going forward, APL's PBILDT margin is expected to be supported by improvement in the operational performance of both international generic business and domestic branded generic business. Recently, India's drug pricing authority has allowed a price hike of around 10.7% on Drug Price Control Order (DPCO) products owing to the increasing cost of raw material, which shall help the company to maintain its gross margin to some extent. The PBILDT margin is expected to remain healthy at around 20%-22% in the near to medium term. APL is currently capitalising majority of its pre-operating expenses related to its new manufacturing facilities. Until these new manufacturing facilities start meaningful contribution in the total revenue, APL's PBILDT margin is expected to be impacted in the near to medium term. Furthermore, post-acquisition of 100% stake in ADL, APL has wrote-off ADL's accumulated intangible assets of ₹188 crore, which impacted the consolidated net profit during FY22. The management of APL has also indicated the additional write-off of ADL's intangible assets of nearly ₹150-155 crore during FY23, which would also impact its consolidated net profit in FY23.

Comfortable capital structure and debt coverage indicators: APL has a strong net-worth base of ₹5,181 crore as on March 31, 2022, whereas its reliance on external debt (including lease liabilities) stood at ₹717 crore as on even date translating into comfortable overall gearing of 0.14x as on March 31, 2022. APL does not envisage any major capex or acquisition until its new manufacturing facilities stabilise and generate meaningful returns. Its expected cash accruals are adequate to meet its envisaged capex and working capital requirement. Hence, APL's overall gearing is expected to remain below 0.20x in the medium term. APL's debt coverage indicators also remain comfortable marked by total debt/PBILDT of 0.69x and total debt to gross cash accruals (TD/GCA) of 0.79 years during FY22. The debt coverage indicators are expected to remain comfortable due to APL's healthy profitability and no major increase in total debt envisaged in the near to medium term.

Stable demand growth prospects for IPI: 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.

Key rating weaknesses

Continued delay in commencement of commercial operations of various new projects: Few years ago, APL had initiated setting-up of three new manufacturing facilities targeted for catering the regulated markets. APL's management has articulated that all the new manufacturing facilities are ready to be put to use; however, there is delay in the commencement of their commercial operations due to delay in the receipt of regulatory approvals from the United States Food and Drug Administration (USFDA). One of the newly set-up facilities was re-inspected in November 2021 and received 10 observations by the USFDA. As articulated by the management of APL, all the observations are procedural in nature and the remedial measures are underway. The company is still awaiting the USFDA inspection for its other two newly set-up facilities. The delay in USFDA audit is also on account of the outbreak of the COVID-19 pandemic. APL now expects one of its manufacturing facilities to start commercial operations by H2FY23 and remaining two manufacturing facilities are expected to commence commercial operations thereafter. Furthermore, after the commencement of commercial operations, the optimum capacity utilisation and deriving envisaged benefits remain key monitorables given the highly regulated and competitive US generic market and delays in product approvals. Timely commercialisation of its new manufacturing facilities along with generating adequate returns on the capital deployed in the ongoing capex will be crucial for maintaining healthy financial risk profile of APL.

Inherent regulatory risk associated with pharmaceutical industry: APL derived around 36% of its revenue during FY22 from domestic formulation business. Also, around 21.5% of its formulations feature in the National List of Essential Medicine (NLEM). Inclusion of any fresh formulations in NLEM and consequently in DPCO may restrict the pricing flexibility for APL. It is also exposed to the regulatory changes in global markets (primarily USA) as international generic business contributed nearly 46% to its revenue during FY22. Continuous efforts by the US government to bring down drug prices, intense competition in US generic market and consolidation of US pharmaceutical distributors, may pose vulnerability to its profitability. 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. APL's new injectable manufacturing facility was issued 10 audit observations by USFDA during its audit in November 2021. However, the company management has indicated that all the observations were procedural in nature and the remedial measures are underway.

Liquidity: Strong

APL's liquidity is expected to remain strong in the absence of long-term debt repayment obligation as on May 31, 2022. APL has already fully repaid its non-convertible debenture during April 2022. APL's liquidity indicator also continued to remain strong marked by current ratio of 1.61x as on March 31, 2022. Furthermore, APL's internal accruals are expected to remain adequate to meet its capex and working capital requirement. The utilisation of its fund-based working capital limits including commercial paper also remained low at around 23% for the trailing 12 months ended April 2022. Its un-utilised working capital limits provides additional liquidity cushion. This apart, its healthy net-worth base and comfortable leverage provide significant financial flexibility to APL.

Analytical approach: Consolidated.

For analytical purpose, 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, 2022, are mentioned in **Annexure 4**.

Applicable criteria

Criteria for short term instruments
CARE's policy on default recognition
CARE's methodology for manufacturing companies
Rating methodology - pharmaceutical sector
Rating methodology: Consolidation
Financial ratios – non-financial sector
Liquidity analysis of non-financial sector entities

About the company

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 in to 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.

Brief Financials - Consolidated (₹ crore)	FY21 (A)	FY22 (A) *
Total operating income	5,470	5,350
PBILDT	1,558	1,041
PAT	1,147	521
Overall gearing (times)	0.12	0.14
PBILDT interest coverage (times)	97.23	58,74

A: Audited * Abridged published results on stock exchange

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 the rated instruments/facilities: Not applicable

Complexity level of various instruments rated for this company: Annexure-3

Annexure-1: Details of instruments/facilities

Name of the Instrument	ISIN	Date of Issuance	Coupon Rate	Maturity Date	Size of the Issue (₹ crore)	Rating Assigned along with Rating Outlook
Commercial Paper-Commercial Paper (Standalone)	-	-	-	7 to 364 days	750.00	CARE A1+

Annexure-2: Rating history of last three years

Sr. No.	Name of the Instrument/Bank Facilities	Current Ratings			Rating History			
		Type	Amount Outstanding (₹ crore)	Rating	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	Date(s) and Rating(s) assigned in 2019-2020
1	Commercial paper-Commercial paper (Standalone)	ST	750.00	CARE A1+	-	1)CARE A1+ (22-Jun-21)	1)CARE A1+ (25-Jun-20)	1)CARE A1+ (22-Jul-19)

Annexure 3: Complexity level of various instruments rated for this company

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

Annexure-4: List of entities consolidated in APL as on March 31, 2022

<table>
<tr><th>Sr. No.</th><th>Name of the entity</th><th>% of Holding as on March 31, 2022</th><th>Relationship</th></tr>
<tr><td>1</td><td>Alembic Global Holding SA (AGH)</td><td>100%</td><td rowspan="3">Subsidiaries of APL</td></tr>
<tr><td>2</td><td>Alembic Pharmaceuticals (AP) Inc.</td><td>100%</td></tr>
<tr><td>3</td><td>Aleor Dermaceuticals Limited</td><td>100%</td></tr>
<tr><td>4</td><td>Alembic Pharmaceuticals Europe Limited</td><td>100%</td><td rowspan="7">Step-down subsidiaries</td></tr>
<tr><td>5</td><td>Alembic Pharmaceuticals Canada Limited</td><td>100%</td></tr>
<tr><td>6</td><td>Alembic Pharmaceuticals Australia Pty Limited</td><td>100%</td></tr>
<tr><td>7</td><td>Alnova Pharmaceuticals SA</td><td>100%</td></tr>
<tr><td>8</td><td>Genius LLC</td><td>100%</td></tr>
<tr><td>9</td><td>Alembic Labs LLC</td><td>100%</td></tr>
<tr><td>10</td><td>Okner Realty LLC</td><td>100%</td></tr>
<tr><td>11</td><td>Incozen Therapeutics Pvt. Ltd.</td><td>50%</td><td>Associate of APL</td></tr>
<tr><td>12</td><td>Rhizen Pharmaceuticals SA (RPSA)</td><td>50%</td><td>Associate of AGH</td></tr>
<tr><td>13</td><td>Dahlia Therapeutics SA</td><td>50%</td><td rowspan="2">Subsidiary of RPSA</td></tr>
<tr><td>14</td><td>Rhizen Pharmaceuticals Inc.</td><td>50%</td></tr>
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Annexure-5: Bank lender details for this company

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

Note on 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:

Established in 1993, CARE Ratings is one of the leading credit rating agencies in India. Registered under the Securities and Exchange Board of India, it has been acknowledged as an External Credit Assessment Institution by the RBI. With an equitable position in the Indian capital market, CARE Ratings provides a wide array of credit rating services that help corporates raise capital and enable investors to make informed decisions. With an established track record of rating companies over almost three decades, CARE Ratings follows a robust and transparent rating process that leverages its domain and analytical expertise, backed by the methodologies congruent with the international best practices. CARE Ratings has played a pivotal role in developing bank debt and capital market instruments, including commercial papers, corporate bonds and debentures, and structured credit.

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