Dating



Zydus VTEC Limited

June 10, 2022

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Facilities	Amount (₹ crore)	Rating ¹	Rating Action	
Long-term bank facilities	250.00 [@]	CARE AA+ (CE); Positive [Double A Plus (Credit Enhancement); Outlook: Positive]	Assigned	
Total bank facilities	250.00 (₹ Two hundred fifty crore only)			

Details of instruments/facilities in Annexure-1.

@Backed by credit enhancement in the form of unconditional and irrevocable corporate guarantee of Zydus Lifesciences Limited.

Unsupported Rating

CARE A (Single A) [Assigned] Note: Unsupported Rating does not factor in the explicit credit enhancement.

Detailed rationale and key rating drivers for the credit enhanced debt

The rating assigned to the bank facilities of Zydus VTEC Limited (ZVTEC) is based on the credit enhancement in the form of unconditional and irrevocable corporate guarantee (CG) provided by Zydus Lifesciences Limited (ZLL or 'guarantor'). The above rating (supported rating) is solely based on CARE Ratings Limited's (CARE Ratings) view of the guarantor's credit profile, and accordingly, the rating rationale highlights the key credit risk assessment parameters for the guarantor. The rating remains sensitive to any variation in the credit profile of ZLL.

Detailed rationale and key rating drivers of ZLL

The ratings assigned to the bank facilities of Zydus Lifesciences Limited (consolidated, hereafter referred to as 'the group') draw strength from the experienced promoters and management with a long and successful track record in the pharmaceutical industry, the strong and diversified product portfolio along with a bouquet of well-established brands catering to multiple therapeutic segments across various geographies, and its significant presence in the wellness segment. These strengths are further augmented by the group's accredited manufacturing facilities, well-equipped research and development (R&D) facilities, and a healthy financial risk profile, marked by consistent growth in the scale of operations, strong liquidity, and a strong capital structure.

The credit profile of ZLL is, however, constrained by the group's exposure to regulated markets, which have been witnessing increased competition and pricing pressure in the generics space, the drug price regulations prevalent in India, the susceptibility of operating margins to raw material price fluctuations, and the inherent regulatory risk associated with the pharmaceutical industry.

Key rating drivers of Zydus VTEC Limited, ie, for the Unsupported Rating

The rating assigned to the bank facilities of ZVTEC derives strengths from its experienced and established promoters, the strong pipeline of biosimilars and new chemical entities (NCEs), and the strong financial and managerial support from the parent, ZLL. These strengths, however, continue to remain constrained by the intense competition in the vaccine space, the nascent stage of operations of the company, and the regulatory risks inherent to the sector.

Rating sensitivities of ZLL

Positive factors – Factors that could lead to positive rating action/upgrade:

- Sustained growth in the turnover by more than 10% along with improvement in its profitability margins.
- Improvement in the total debt/PBILDT to below unity and substantial improvement in the revenue of the subsidiary companies.

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

- Decline in the operating profitability to below 15%, either due to increased competition or regulatory issues.
- Large debt-funded capex or acquisition, leading to net debt/PBILDT over unity.
- Credit metrics deteriorating significantly because of large debt-funded capex or acquisitions, with overall gearing increasing ٠ beyond 0.50x.

Outlook: Positive

The outlook is 'Positive', based on CARE Rating's expectation of an improvement in ZLL's business and financial risk profiles in the medium term, marked by steady growth in its scale of operations and healthy cash generation, resulting in an improved overall gearing. The outlook may be revised to 'Stable' if there is a sizeable decline in ZLL's profitability or any material adverse impact on its debt coverage indicators due to a large-size acquisition or capex or any other event.

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



Detailed description of the key rating drivers – ZLL

Key rating strengths

Experienced management with a long and successful track record in the pharmaceutical industry: Cadila Laboratories was founded in 1952 by the late Ramanbhai B Patel and the late Indravadan A Modi. In 1995, the company was restructured and thus was formed Cadila Healthcare Limited (CHL) under the aegis of the Zydus group. In February 2000, CHL went public and got listed on the Bombay Stock Exchange (BSE). In February 2022, the Zydus group announced its new brand identity with CHL to be known as Zydus Lifesciences Limited (ZLL). As on March 31, 2022, the promoters held 74.88% of shares in ZLL. ZLL, the flagship company of the Zydus group, is headed by its Chairman Mr. Pankaj R Patel.

Diversified geographical and manufacturing presence: The group's global business has presence in the regulated markets of the US, Europe, and in the emerging markets (EM) of Latin America, South Africa, and Asia. As on March 31, 2021, it had 37 subsidiaries and three joint ventures (JVs) incorporated in various countries of the world. The domestic market comprises formulations and consumer wellness businesses and contributed a revenue of ₹6,791 crore in FY22, which accounted for 46% of the group's revenues. The US formulations business is the second-largest contributor to the group revenue, with ₹5,814 core in FY22, which accounted for 39% of the group's revenue. The revenues from the US formulations business registered a year-on-year moderation of 8% owing to intense pricing pressure and the rising competition in the generics space. However, it maintained the top three ranking in almost 60% of the group's revenues. The EM formulations business witnessed a year-on-year growth of 17%, representing the group's strong growth in those markets.

The group has 36 manufacturing plants, spread across the five states of Gujarat, Maharashtra, Goa, Himachal Pradesh, and Sikkim, in India, and in the US and Brazil. Of the total 36 manufacturing facilities, 30 facilities are for manufacturing finished dosage formulations and active pharmaceutical ingredients (APIs). Out of these 30 facilities, 14 have been inspected by the United States Food and Drug Administration (USFDA). The plant for the Zycov-D vaccine is set up at the Zydus Vaccine Technology Excellence Centre at the Zydus Biotech Park in Changodar, Ahmedabad, and was commissioned in June 2021. The plant has a capacity of manufacturing 1 crore vials per month and has started manufacturing drug substances for Zycov-D from December 2021.

Established brands across multiple therapeutic and wellness segments with a strong focus on research and development: In the domestic formulation segments, ZLL has a presence in various therapeutic segments, viz, anti-infective, cardiac, gastro-intestinal, respiratory, gynaecology, pain management, dermatology, among others, with the maximum revenue coming from the anti-infective segment. ZLL's brands are well-established and command a high valuation. In the consumer wellness segment, the group retained its leadership position in five out of six brands in their respective categories in FY22. The major brands in the wellness segment include Nycil, Sugarfree, Everyuth, Nutralite, Glucon-D, Complan, with a distribution network of half-a-million outlets. In the US formulations business, ZLL was ranked fifth among the US generic companies, based on prescriptions in FY21. Even with the increased competition and pricing pressure in the US market, ZLL maintained a top three ranking in about 60% of the product families. ZLL has received approvals for 28 abbreviated new drug applications (ANDAs), including 10 tentative approvals, and has filed 26 new ANDAs during FY22, taking the cumulative approvals and filings to 312 and 420, respectively.

The company has eight R&D facilities for NCE, API, Gx formulations, biosimilars, and vaccines. With over 1,400 scientists and significant investments in the R&D space (₹1,041 crore in FY22, equivalent to almost 7% of the total operating income (TOI)), ZLL continues to strive toward innovation. ZVTEC was the first to get approval for the use of DNA-based vaccine against COVID-19. ZLL launched 30 new products in the US in FY21. It has received approval from USFDA to market pemetrexed for injection used to treat certain kinds of cancer.

Strong financial risk profile: The TOI of ZLL (consolidated) witnessed a nominal growth of 1% in FY22, to reach ₹15,265.20 crore vis-à-vis ₹15,102.20 crore in FY21. The PBILDT margin has moderated marginally in FY22, to 21.88% as against 22.15% in FY21, albeit still at a healthy level. The margin reduced in FY22 primarily on account of the increase in raw material costs and the pricing pressure in the US market. ZLL has a favourable capital structure with a strong net worth base. The overall gearing improved to 0.34x as on March 31, 2022, from 0.55x as on March 31, 2021, owing to the substantial reduction in debt with commercial paper (CP) of ₹650 crore getting extinguished and term loans getting repaid. The debt to equity ratio of the company improved to 0.07 as on March 31, 2022, from 0.18 as on March 31, 2021, owing to the reduction in long term debt. The company turned net debt negative, as on March 31, 2022, supported by strong cash accruals and cash inflow from the sale of the animal health business in India. With no major debt-funded capex planned in the near future and regular capex expenses expected to be met out of internal accruals, the debt to equity ratio is expected to improve in the future.

Healthy cash and bank balance and current investments leading to strong liquidity: ZLL has a healthy cash and bank balance of ₹1,107 crore as on March 31, 2022. It further has liquid investments to the tune of ₹2,353 crore, primarily invested in mutual funds, ₹513 crore as deposits, and ₹338 crore as marketable investments, as on March 31, 2022. Furthermore, the company is earning healthy cash accruals year-on-year, which is aiding in building the net worth base and liquidity for the company. ZLL's average working capital has remained around 27% for the last 12 months ending March 31, 2022, providing it further financial flexibility.



Divestment of stake in India's animal health business entity led to significant improvement in liquidity profile of the group

Zydus Animal Health and Investments Ltd (ZAHL) entered into a business transfer agreement (BTA) to sell and transfer its Animal Healthcare Established Markets Undertaking (AHESTM) focused on India and other countries' animal health business to Zenex Animal Health India Private Limited, a special purpose vehicle (SPV) owned by a Multiples Alternate Asset Managementled consortium, on a slump sale basis as a going concern, for a lump sum consideration of ₹2,921 crores in May 2021. The group intends to utilise the cash generated from this transaction for pursuing the strategic objectives in India and the US geographies and advance its innovation-led programmes in NCEs, biosimilars, vaccines, and specialty areas. In the short term, the available liquidity will help ZLL deleverage its balance sheet by reducing net debt.

Key rating weaknesses

ZLL's substantial investment in group entities: ZLL, on a standalone basis, had investments of ₹4,897 crore as on March 31, 2022 towards group and related entities, which decreased from ₹6,373 crore as on March 31, 2021, which turns to 37% and 50% of the TNW of ZLL as on March 31, 2022 and March 31, 2021, respectively. Any adversity on the credit profile of the group companies is likely to transcend to commensurate adversity for the credit profile of ZLL. However, the group entities are an integral part of the business operations of ZLL, which ensures that the group companies manage their obligations.

Price regulations in emerging countries like India: The National Pharmaceutical Pricing Authority (NPPA) is entrusted with the task of fixation/revision of prices of pharma products, the enforcement of provisions of the Drugs Prices Control Order (DPCO), and the monitoring of prices of controlled and decontrolled drugs. As stipulated under the DPCO 2013, NPPA fixes the ceiling price of essential medicines of Schedule-I. In respect of medicines not under price control, the manufacturers are allowed to increase the maximum retail price by 10% annually. The calculation for essential drugs is based on the simple average of all medicines in a particular therapeutic segment, with sales of more than 1%. While about 20-22% of the domestic product portfolio is under the DPCO purview, the group's strong brands and regular product launches will continue to support the domestic revenue growth over the medium term. The inclusion of ZLL's other formulations in the DPCO may impact the profitability margin.

Regulatory risk and intense competition in the pharmaceutical industry: The company is exposed to regulatory risk, with its operations into manufacturing pharmaceutical formulations along with APIs. In India, the government also controls the prices of pharmaceutical products through the DPCO under the price control mechanism. Besides, the pharmaceutical industry is highly regulated in many other countries and requires various approvals, licenses, registrations, and permissions for business activities. The approval process for a new product registration is complex, lengthy, and expensive. The time taken to obtain approvals vary by country, but generally takes from six months to several years from the date of application. Any delay or failure in getting approval for a new product launch can adversely affect the business prospects of the company. Given India's significant share in the US' generic market, the USFDA has increased its scrutiny of manufacturing facilities and other regulatory ban on the products or facilities and may impact a company's future approvals from the USFDA. For example, the USFDA issued a warning letter to Moraiya Formulations' facility in November 2019. ZLL completed the remediation measures to address the observations raised by the USFDA in FY21 and the final update was submitted to the USFDA in November 2020. The company, on account of the above development, had to transfer injectable products from Moraiya Formulations' facility to the injectable formulations facility of Liva near Baroda.

Liquidity of ZLL: Strong

The liquidity profile of ZLL is strong, aided with healthy cash accruals from operations in excess of ₹2,500 crore per annum. ZLL has a healthy cash and bank balance of ₹1,106.90 crore, as on March 31, 2022. ZLL further has liquid investments to the tune of ₹2,353 crore, as on March 31, 2022, primarily invested in mutual funds. Furthermore, the company is earning healthy cash accruals year-on-year, which is aiding in building the net worth base and liquidity for the company. The overall gearing improved to 0.34x as on March 31, 2022, from 0.55x as on March 31, 2021, owing to substantial reduction in debt, with CP of ₹650 crore getting extinguished and term loans getting repaid. The debt to equity ratio of the company improved to 0.07 as on March 31, 2022, from 0.18 as on March 31, 2021, owing to the reduction in the long term debt. The company turned net debt negative as on March 31, 2022, supported by strong cash accruals and cash inflow from the sale of the animal health business in India. With no major debt-funded capex planned in the near future and regular capex expenses expected to be met out of internal accruals, the debt to equity ratio is expected to improve in the future; nevertheless, there is adequate headroom that is available in case the company plans to avail debt. ZLL's average working capital has remained around 27% for the last 12 months ending March 31, 2022, providing it further financial flexibility.

Liquidity of ZVTEC: Adequate

The liquidity position of the company is adequate. The company started manufacturing drug substance for Zycov-D vaccine from December 2021 and supply against the Government of India's (GoI) order of 1 crore vaccines started in January 2022. While the operations of the company are at a nascent stage, it expects the revenue and cash accruals to improve in FY23 from the export of vaccines and from the sale of other biosimilar and NCE products. However, the facilities availed by the company are backed by an unconditional and irrevocable CG of ZLL.



Analytical approach

For CE rating: Assessment of the guarantor

CARE Ratings has analysed ZVTEC's credit profile by considering the financial statements of ZLL (consolidated) owing to the unconditional and irrevocable CG extended by ZLL for the bank facilities of ZVTEC.

For Unsupported rating: Standalone

Applicable criteria

Policy on Default Recognition Financial ratios – Non-financial sector Liquidity analysis of non-financial sector entities Rating outlook and credit watch Pharmaceutical Factoring linkages parent sub JV group Rating credit enhanced debt

About the company – ZLL

Cadila Laboratories was found in 1952 by the late Ramanbhai B Patel and the late Indravadan A Modi. In 1995, the company was restructured and thus was formed Cadila Healthcare Limited (CHL) under the aegis of the Zydus group. In February 2000, CHL went public and got listed on the BSE. In February 2022, the Zydus group announced its new brand identity with CHL to be known as Zydus Lifesciences Limited (ZLL). As on March 31, 2022, the promoters held 74.88% of shares in ZLL. ZLL, the flagship company of the Zydus group, is headed by its Chairman Pankaj R Patel. The group is engaged in manufacturing formulations and APIs across multiple therapeutic segments and various geographies. The company is managed by an eight member board of directors with four independent directors.

About the company – **ZVTEC**

ZVTEC, established in September 2020, is a wholly-owned subsidiary of ZLL. Located at the Zydus Biotech Park in Changodar, Ahmedabad, ZVTEC is engaged in manufacturing the drug substance for the needle-free DNA Plasmid vaccine – ZyCoV-D – the COVID-19 vaccine.

Brief Financials of ZLL (₹ crore)	March 31, 2020 (A)	March 31, 2021 (A)	March 31, 2022 (Prov)
TOI	14,253.10	15,102.20	15,265.20^
PBILDT	2,798.10	3,344.50	3,340.70^
PAT	1,204.40	2,185.00	4,618.30*^
Overall gearing (times)	1.62	0.55	0.34#
Interest coverage (times)	8.19	20.46	26.30 [#]

A: Audited Prov: Provisional.

^Based on audited figures for the financial year ending March 31, 2022, as published by ZLL.

#As the audited annual report for ZLL is not available as on the date of publication of this report, these numbers are mentioned as Provisional. *Including ₹2,245.70 crore profit from discontinued operations.

Brief financials of ZVTEC

The company started commercial operations from December 2021. Hence, the FY21 financials are not meaningful. The company has not shared FY22 provisional financials.

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

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

Covenants of rated instruments/facilities: Detailed explanation of the covenants of the rated instruments/facilities is given in Annexure-3

Complexity level of various instruments rated for this company: Annexure-4



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
Term Loan-Long Term		-	-	November 2026	250.00	CARE AA+ (CE); Positive
Unsupported Rating- Unsupported Rating (Long Term)		-	-	-	0.00	CARE A

Annexure-2: Rating history for the last three years

		Current Ratings			Rating History			
Sr. No.	Name of the Instrument/Bank Facilities	Туре	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	Term Loan-Long term	LT	250.00	CARE AA+ (CE); Positive				
2	Unsupported Rating- Unsupported Rating (Long term)	LT	0.00	CARE A				

*Long term/short term

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

Annexure-4: Complexity level of various instruments rated for this company

Sr. No.	Name of Instrument	Complexity Level
1	Term Loan-Long term	Simple
2	Unsupported Rating-Unsupported Rating (Long term)	Simple

Annexure-5: Bank lender details for this company

To view the lender-wise details of bank facilities, please <u>click here</u>.



Annexure-6: List of subsidiaries and JVs considered for consolidation

Sr. No.	Name of Companies/Entities	Percentage of Holding (%)
Subsidia	ries	
1	Zydus Wellness Limited	57.59
2	Zydus Wellness Products Limited	57.59
3	Zydus Healthcare Limited	100.00
4	Zydus Pharmaceuticals Limited (#)	100.00
5	Biochem Pharmaceutical Private Limited (#)	100.00
6	Dialforhealth Unity Limited	55.00
7	Dialforhealth Greencross Limited	100.00
8	German Remedies Pharmaceuticals Private Limited	100.00
9	Liva Investment Limited	57.59
10	Liva Nutritions Limited	57.59
11	Violio Healthcare Limited (#)	100.00
12	Zydus Animal Health and Investments Limited	100.00
13	Zydus Strategic Investments Limited	100.00
14	Zydus VTEC Limited	100.00
15	Zydus Lanka (Private) Limited	100.00
16	Zydus Healthcare Philippines Inc.	100.00
17	Zydus International Private Limited	100.00
18	Zydus Netherlands B.V.	100.00
19	Zydus France, SAS	100.00
20	Laboratorios Combix S.L.	100.00
21	Etna Biotech S.R.L.	100.00
22	Viona Pharmaceuticals (USA) Inc.	100.00
23	Zydus Pharmaceuticals (USA) Inc. (\$)	100.00
24	Zydus Healthcare (USA) LLC	100.00
25	Sentynl Therapeutics, Inc.	100.00
26	Zydus Noveltech Inc.	100.00
27	Hercon Pharmaceuticals LLC	100.00
28	Zydus Worldwide DMCC	100.00
29	Zydus Discovery DMCC	100.00
30	Zydus Wellness International DMCC	100.00
31	Zydus Healthcare S.A. (Pty) Ltd	100.00
32	Simayla Pharmaceuticals (Pty) Ltd	100.00
33	Script Management Services (Pty) Ltd	100.00
34	Zydus Nikkho Farmaceutica Ltda.	100.00
35	Alidac Healthcare (Myanmar) Limited (#)	100.00
36	Zydus Pharmaceuticals Mexico SA De CV	100.00
37	Zydus Pharmaceuticals Mexico Services Company SA De C.V.	100.00
JVs		
1	Zydus Hospira Oncology Private Limited	50.00%
2	Zydus Takeda Healthcare Private Limited	50.00%
3	Bayer Zydus Pharma Private Limited	24.99%

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:

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