Genesys Biologics Private Limited

October 3, 2024

Facilities/Instruments	Amount (₹ crore)	Rating[1]	Rating Action
Long-term bank facilities	70.00	CARE C; ISSUER NOT COOPERATING*	Rating moved to ISSUER NOT COOPERATING category

Details of instruments/facilities in Annexure-1.
*Issuer did not cooperate; based on best available information.

Rationale and key rating drivers

CARE Ratings Limited (CARE Ratings) has been seeking information from Genesys Biologics Private Limited (GBPL) to monitor the rating(s) vide e-mail communications dated July 03, 2024, July 15, 2024, September 06, 2024, September 18, 2024, September 20, 2024, September 26, 2024, and September 27, 2024, and numerous phone calls. However, despite repeated requests, the company has not provided requisite information for monitoring ratings. In line with the extant Securities and Exchange Board of India (SEBI) guidelines, CARE Ratings has reviewed the rating based on best available information, which however, in CARE Ratings' opinion is not sufficient to arrive at a fair rating. Ratings on GBPL's bank facilities will now be denoted as **CARE C; ISSUER NOT COOPERATING*.**

Users of this rating (including investors, lenders, and public at large) are hence requested to exercise caution while considering these rating(s).

Ratings have been revised and migrated to INC category due to non-availability of requisite information due to non-cooperation by Genesys Biologics Private Limited (GBPL) with CARE Ratings' efforts to undertake a review of the rating outstanding. CARE Ratings views information availability risk as a key factor in its assessment of credit rating.

Analytical approach: Standalone

Outlook: Not applicable

At the time of last rating on September 08, 2023, following were rating weaknesses and strengths.

Detailed description of key rating drivers:

Key weaknesses

Short track record and significant delay in completion of project

The company has a short track record although established in 2014, commercial operations yet to be started. The company has faced liquidity issues in the past due to delay in project execution considering delay in receipt of statutory approvals from authorities resulted in mismatch in cash flows leads to delays in meeting debt obligation.

The commencement of operations at the company's bio-similar plant has been delayed, operations were expected to begin from December 2022, which however, was delayed due to delay in approvals from authorities.

Inherent implementation and stabilisation risks associated with its planned greenfield project

Currently, the company has undertaken a project for setting up facility with total project cost of ₹450 crore funded partly from CIVICA milestone-based payments/capital assistance, unsecured loans from promoters and loans from DFC (U.S. International Development Finance Corporation). CIVICA will incur all regulatory cost and approvals required from authorities. The company expecting project completion in the next two years. However, timely infusion of funds, sources and project completion will remain critical from a credit perspective.

[1]Complete definition of ratings assigned are available at www.careedge.in and other CARE Ratings Limited's publications.

Exposure to regulatory risk

The company is exposed to regulatory risk as the pharmaceutical industry is highly regulated in many other countries and requires approvals, licenses, registrations and permissions for business activities. The approval process for a new product registration is complex, lengthy and expensive. The company's ability to continue to observe the regulatory and CGMP standards without receiving critical observations from regulatory authorities are viewed critically from business and credit risk point of view.

Key strengths

Resourceful and experienced promoters

GBPL has been promoted by Rajender Rao Juvvadi (Chairman) is a Mechanical Engineering from Osmania University 1988 Postgraduate from Indian Institute of Foreign Trade (IIFT) New Delhi 1992. He ventured this new entity Aurore Life Sciences Private Limited with an aggressive growth plan, which is now merged with India's second largest API Manufacturer Solara Active Pharma Limited. He was also, executive director for Solara Active Pharma Sciences Limited.

Venkat Reddy Yelma (Managing Director), MS in Regulatory Affairs (Drugs, Biologics & Devices) from Northeastern University, USA has over 20+ years of experience across companies. He is a value-driven biopharma executive with proven expertise in drug development, organisational leadership and successful in developing and implementing global regulatory affairs in the US and Singapore-based firms – ImClone, Bayer & Merck (Formerly Schering-Plough). The operations are further supported by other directors Dr Venkata Krishna Rao holds over 20 years of experience in Biopharma with Wockhardt, Natco and Krebs. Tulasi Ramu has 20+ years of experience in Biopharma industry, having previously worked with large-scale companies including Wockhardt, SciGen and Dr. Reddy's Laboratories Limited.

CO-development and commercialisation agreement with CIVICA

CIVICA entered a co-development and commercial agreement with GBPL for these three (glargine, lispro and aspart) insulin biosimilars on February 03, 2022. Civica will use drug substance produced in partnership with GBPL and will have exclusive rights in the US to market and sell these insulins at costs that are substantially lower than what is currently available in the US. The company receives payment from CIVICA as capital assistance/milestones for commissioning the proposed facility. As on March 31, 2023, the company had received ₹90.59 crore, milestone income of ₹17 crore was not received in FY23 due to delay in the completion of Phase -1 trials.

Stable Industry outlook

Increasing prevalence of Type I diabetes, higher cost of existing insulin drugs are expected to drive growth of insulin biosimilars market. Government authorities are also focusing on approval of insulin biosimilars owing to substantial financial burden in terms of reimbursements. Recently, the US FDA has approved new insulin glargine Basaglar, for type 1 and type 2 diabetes, which is Biosimilar version of Sanofi's basal insulin Lantus (insulin glargine). Lilly and Boehringer Ingelheim's biosimilar insulin glargine has been approved through European Medicines Agency's (EMA's) Biosimilar pathway. Such ongoing approvals by respective authorities are expected to drive growth of the insulin Biosimilar market.

Liquidity: Stretched
Liquidity is marked by tightly matched accruals to repayment obligations since operations are yet to be commercialised, resulting in negative cash accruals. The company has cash and bank balance of ₹68 crore as on March 31, 2023, considering receipt of milestone funds from CIVICA. Average utilisation of bank limits remained ~80% for 12-months ended July 31, 2023.

Assumptions/Covenants: Not applicable

Environment, social, and governance (ESG) risks: Not applicable

Applicable criteria

Definition of Default
Policy in respect of non-cooperation by issuers
Rating Outlook and Rating Watch
Manufacturing Companies
Pharmaceuticals
Financial Ratios – Non financial Sector
Project stage companies

About the company and industry

Macroeconomic indicator	Sector	Industry	Basic industry
Healthcare	Healthcare	Pharmaceuticals & biotechnology	Pharmaceuticals

Incorporated 2014, GBPL is a privately held biotechnology company with dedicated focus on Research and Development of Insulin Biosimilars derived from indigenously developed process and customised manufacturing platform, which is capable for yielding all Insulin variants such as Glargine (Long Acting), Aspart (Rapid Acting), Lispro (Short Acting) at its pilot facility in Hyderabad. GBPL has well-equipped R&D and pilot scale facility at Genome Valley, Biotech Park, Shameerpet Hyderabad with the built-up area of five acres and secured additional five acres of land for manufacturing facility for commercial production.

The company successfully completed toxicology studies (Pre-Clinical Studies) for four products and progressing towards Clinical Trial approvals in India. One of the Product – Glargine, had successfully completed Clinical Trails Phase – I in India and Phase – III Clinical trials, which was expected to be completed by December 2022 is delayed due to appointment of new Contract research organisation (CRO) and approvals from authorities. Genesys is expected to complete trials by February 2024 and commercial operations can be started from June 2024.

Brief Financials (₹ crore)	March 31, 2022 (A)	March 31, 2023 (P)	FY24 (UA)
Total operating income	34.13	2.48	NA
PBILDT	0.31	-52.19	NA
PAT	-19.61	-69.83	NA
Overall gearing (times)	2.74	-15.30	NA
Interest coverage (times)	0.03	-6.36	NA

A: Audited UA: Unaudited, NA: Not available, P: Provisional Note: these are latest available financial results

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

Rating history for last three years: Annexure-2

Detailed explanation of covenants of rated instrument / facility: Annexure-3

Complexity level of instruments rated: Annexure-4

Lender details: Annexure-5

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 and Rating Outlook
Fund-based - LT-Cash Credit		-	-	-	11.00	CARE C; ISSUER NOT COOPERATING*
Fund-based - LT-Term Loan		-	-	June 2026	59.00	CARE C; ISSUER NOT COOPERATING*

*Issuer did not cooperate; based on best available information.

Annexure-2: Rating history for 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 2024-2025	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
1	Fund-based - LT-Term Loan	LT	59.00	CARE C; ISSUER NOT COOPERATING*	-	1)CARE C; Stable (08-Sep-23)	1)CARE BB-; Stable (09-Sep-22)	-
2	Fund-based - LT-Cash Credit	LT	11.00	CARE C; ISSUER NOT COOPERATING*	-	1)CARE C; Stable (08-Sep-23)	1)CARE BB-; Stable (09-Sep-22)	-

*Issuer did not cooperate; based on best available information.
LT: Long term

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

Annexure-4: Complexity level of instruments rated

Sr. No.	Name of the Instrument	Complexity Level
1	Fund-based - LT-Cash Credit	Simple
2	Fund-based - LT-Term Loan	Simple

Annexure-5: Lender details

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

Contact us

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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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