UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 26, 2025

Cellectar Biosciences, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware	**1-36598**	**04-3321804**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

100 Campus Drive, Florham Park, NJ, 07932
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (608) 441-8120

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	**CLRB**	The **Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

In connection with a proposed offering of securities, the Company is providing the following disclosures, which update and supplement the Company's existing disclosures, as follows:

- CLR 125, the Auger-emitting PRC, utilizes iodine-125 and has been observed to show tolerability with minimal toxicities in animal models. Additionally, the Company observed CLR 125 to have good activity in multiple solid tumor models, especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. The Company believes that this means that to cause the necessary breakage of the tumor cell DNA, the isotope most get inside the cell and near the cell nucleus to be effective. The Company believes that CLR 125 achieves this due to the Company's novel phospholipid ether drug conjugate platform. CLR 125 is prepared to be the subject of a Phase 1b dose finding study in the second half of 2025 as described below, subject to our ability to obtain additional financing.

- CLR 225, the alpha-emitting, actinium-225 based PRC has been observed to show activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. The Company observed CLR 121225 to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. The Company also observed that the compound has excellent biodistribution and uptake by the tumor. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, we have observed the compound's proportional dose response with a single dose providing either tumor stasis at the lowest dose tested or tumor volume reduction at the higher doses. The Company is currently prepared to initiate a Phase 1 imaging and dose escalation safety study in the second half of 2025, subject to our ability to obtain additional financing.

Preclinical Evaluations of CLR 125

In preclinical, *in vivo* evaluations of CLR 125, utilizing triple-negative breast cancer (TNBC) models, the compound was observed to have tumor uptake at a substantially higher rate than that of healthy tissue. Additionally, no signs of end-organ toxicity were observed, including hematological toxicity.

CLR 125 Proposed Study

The anticipated use of funds generated from the Company's proposed offering is to provide necessary capital for operating expenses and to initiate a Phase 1b clinical study in TNBC with CLR 125, which is chemically and structurally the same as iopofosine, with the only difference being the iodine isotope with which it is radiolabeled. The clinical experience of iopofosine informs the biodistribution of the compound and may instruct the potential potency and side effects of CLR 125, although given the different physical properties of the emissions from CLR 125, the Company believes that side effects could be less.

We expect the study to be a Phase 1b, randomized, open-label, multi-center study comparing the safety and efficacy of CLR125 in patients with advanced TNBC who are relapsed/refractory (r/r) to at least one prior therapy. Three dose levels will be assessed in parallel, with enrollment of patients in a 1:1:1 manner. We expect that each arm will have a minimum of 15 evaluable patients. CLR125 will be administered as a fractionated dose on Day 1 and Day 3 for cycle 1 and repeat approximately every 8-week for subsequent cycles. Depending on arm assignments, patients will receive between two and four cycles. An expansion arm may be evaluated of at least 15 patients following evaluation of the three dose levels by the data monitoring committee (DMC).

We anticipate a maximum of 75 patients to be enrolled in the trial. Safety and tolerability of CLR 125 will be assessed by physical examination, Eastern Cooperative Oncology Group (ECOG) performance status, vital signs, laboratory changes over time, ECGs, and adverse events of special interest. Efficacy of CLR 125 will be assessed by CT (or MRI if needed) examinations obtained at six-week intervals following the initial dose of CLR 125.

The study objective is to determine the Phase 2 dosing level with secondary endpoints including safety, tolerability, initial response assessment and distribution.

Preclinical Evaluations of CLR 225

In preclinical, *in vivo* evaluations of CLR 225, utilizing a pancreatic cancer model, the compound was observed to reduce tumor volume and improved survival benefit at four different dosing levels. Observed biodistribution exhibited substantial uptake in the tumor while remaining low in healthy tissue.

Clinical Studies in Iopofosine

The CLOVER-1 Phase 2 study of iopofosine, conducted in r/r B-cell malignancies, met the primary efficacy endpoints from the Part A dose-finding portion. The CLOVER-1 Phase 2b study, where iopofosine remains under further evaluation in highly refractory MM and CNSL patients, is closed to enrollment but ongoing with patients in follow-up. Fatalities have occurred in patients post-treatment with iopofosine.

The CLOVER-WaM study was designed as a pivotal registration study evaluating iopofosine in WM patients that were r/r to at least two prior lines of therapy including having failed or had a suboptimal response to a Bruton tyrosine kinase inhibitor (BTKi). The study completed enrollment in the fourth quarter of 2023, and initial top line data from the study was reported in January 2024. CLOVER-WaM was a single-arm study with a target enrollment of 50 patients. Based upon the data from September 2024, the CLOVER-WaM study enrolled a total of 55 patients in the modified Intent to Treat (mITT) population and met its primary endpoint with a major response rate (MRR) of 58.2% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the FDA agreed-upon statistical hurdle of 20%. The overall response rate (ORR) in evaluable patients was 83.6%, and 98.2% of patients experienced disease control. Responses were durable, with median duration of response not reached with 11.4 months of follow-up and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine I 131 monotherapy achieved a 7.3% complete remission (CR) rate in this highly refractory WM population. Overall, 45 (69.2%) patients had prior exposure to at least 3 drug classes and 19 (29.2%) patients had prior exposure to at least 4 drug classes of anti-cancer therapies. Forty-eight (73.8%) patients had prior exposure to a BTKi of which 37 (77.1%) were deemed to be refractory to BTKis. Forty-three (66.2%) patients were exposed to BTKi and anti-CD20 antibody with 25 (58.1%) being refractory to both BTKi and anti-CD-20 antibodies. Thirty-seven (56.9%) patients had prior exposure to BTKi, anti-CD20 antibody, and chemotherapy and 18 (48.6%) patients were refractory to all three classes of drugs, BTKi, anti-CD20 antibody, and chemotherapy. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. The safety population was 65 patients which was composed of patients that received at least a single dose of iopofosine I 131 but did not receive enough drug to be assessed for efficacy. There were 3 (4.6%) patients that experienced treatment-related adverse events (TRAEs) leading to discontinuation. The rates of greater TRAEs observed in more than 10% of patients included thrombocytopenia (56 [86.2%] patients), neutropenia (52 [80.0%] patients), anemia (42 [64.6%] patients) and decreased white blood cell count (21 [32.3%] patients) among hematologic toxicities and fatigue (22 [33.8%] patients), nausea (19 [29.2%] patients and diarrhea (13 [20.0%] patients) among non-hematologic toxicities. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (53 [81.5%] patients), neutropenia (43 [66.2%] patients), anemia (31 [47.7%] patients), decreased white blood cell count (18 [27.7%]), decreased lymphocyte count 8 (12.3%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 10.8%. There were no treatment-related deaths in the study.

The CLOVER-2 Phase 1a pediatric study an open-label, sequential-group, dose-escalation study was conducted internationally at seven leading pediatric cancer centers. The study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The maximum tolerated dose was determined to be greater than 60mCi/m2 administered as a fractionated dose. CLOVER-2 Phase 1b study is an open-label, international dose-finding study evaluating two different doses and dosing regiments of iopofosine in r/r pediatric patients with high grade gliomas. These cancer types were selected for clinical, regulatory and commercial rationales, including the radiosensitive nature and continued unmet medical need in the r/r setting, and the rare disease determinations made by the FDA based upon the current definition within the Orphan Drug Act. This study is partially funded (~$2M) by a National Institutes of Health SBIR grant from the National Cancer Institute.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center (UWCCC) was awarded a five-year Specialized Programs of Research Excellence (SPORE) grant of $12,000,000 from the NCI and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and

tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a six-week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study was to assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. This portion of the study has fully enrolled, and data were reported at the ASTRO 2024 conference on March 2, 2024. Complete remission was achieved in 64% of patients, with an ORR of 73% (n=11). Prior to treatment with iopofosine I 131, six patients had multiple recurrences, and one had metastatic disease, both of which are indicative of poor outcomes. Additionally, in the study we observed durability of tumor control with an overall survival of 73% and progression free survival of 36% at 12 months. Eleven patients (92%) experienced a treatment-related adverse event. Treatment-related adverse events of grade 3 or higher occurring in 20% or more patients were thrombocytopenia (75%), lymphopenia (75%), leukopenia (75%), neutropenia (67%), and anemia (42%). Observed adverse events were consistent with the known toxicity profile of iopofosine I 131, with cytopenias being the most common. All patients recovered. We believe that these data support the notion of enhanced patient outcomes when combining the use of iopofosine I 131 in combination with external beam radiation for a treatment of solid tumors.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELLECTAR BIOSCIENCES, INC.

Date: June 26, 2025

By: /s/ Chad J. Kolean
Name: Chad J. Kolean
Title: Chief Financial Officer
