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): **December 9, 2019**

CELLECTAR BIOSCIENCES, INC.

(*Exact name of registrant as specified in charter*)

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

100 Campus Drive, Florham Park, New Jersey 07932
(*Address of principal executive offices, and zip code*)

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

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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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. ☐

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	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 7.01 REGULATION FD DISCLOSURE

On December 9, 2019, we issued a press releaseannouncing the presentation of fractionated dosing data in 19 patients with relapsed/refractory multiple myeloma. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
99.1	Press release dated December 9, 2019, titled "Fractionated Dosing of CLR 131 in Patients with Relapsed or Refractory Multiple Myeloma Presented at the 61st Annual American Society of Hematology Conference"

SIGNATURE

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.

Dated: December 9, 2019

CELLECTAR BIOSCIENCES, INC.

By: */s/ Dov Elefant*
Name: Dov Elefant
Title: Chief Financial Officer

Exhibit 99.1

Fractionated Dosing of CLR 131 in Patients with Relapsed or Refractory Multiple Myeloma Presented at the 61st Annual American Society of Hematology Conference

- *50% overall response rate in cohort of patients receiving fractionated 37.5 mCi/m^2 dose of CLR 131*
- *31.3% overall response rate in multiple myeloma patients over all dose levels, including single bolus and fractionated doses of CLR 131*

FLORHAM PARK, N.J., December 9, 2019 -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced the presentation of fractionated dosing data in 19 patients with relapsed/refractory multiple myeloma. Dr. Sikander Ailawadhi, M.D., Associate Professor, Division of Hematology/Oncology at Mayo Clinic Florida, presented the data in an oral presentation at the 61st Annual American Society of Hematology (ASH) meeting.

Dr. Ailawadhi's presentation highlighted results from 19 patients with relapsed/refractory multiple myeloma from Cellectar's Phase 1 and Phase 2 CLOVER-1 trial collected prior to July 30, 2019. The data from the oral presentation support prior literature and preclinical data showing that fractionated dosing provides an enhancement of efficacy and safety while reducing adverse events. The patients presented received one of 3 dose levels: a single bolus dose of 31.25 mCi/m^2 or a fractionated dose of 31.25 mCi/m^2 or a higher fractionated dose of 37.5 mCi/m^2 of CLR 131. The fractionated 37.5 mCi/m^2 dose of CLR 131 represents the greatest amount of drug administered to date in the Phase 2 CLOVER-1 trial. The overall response rate (ORR) for all multiple myeloma patients across the 3 dose cohorts was 31.3% and a 100% disease control rate. Patients receiving the higher fractionated 37.5 mCi/m^2 dose demonstrated a 50% ORR with the remaining 50% having minimal responses (greater than a 25% reduction in the surrogate marker of efficacy).

The patients presented had received a median of 4 prior systemic therapies (range 2-13), had a median age of 69 (range 51-83), including 8 females and 11 males and 80% of the patients in the 37.5 mCi/m^2 cohort were either quad or penta-refractory, and all were refractory to daratumumab.

"These data showing a 50% overall response rate in a cohort of heavily pretreated multiple myeloma patients and a 31.3% overall response rate in all dose levels presented is impressive," said Dr. Ailawadhi. "CLR 131 continued to demonstrate a good safety profile with limited off-target effects and the fractionated dosing of CLR 131 showed improved tolerability versus single bolus dosing. While these doses demonstrate beneficial activity, there is the potential that a second cycle or further fractionation could further enhance both efficacy and tolerability."

The primary adverse events (AEs) at all dosing levels were cytopenias and included thrombocytopenia, anemia, and neutropenia. The hematologic AEs were expected, manageable and followed a predictable timeline to nadir (average 40 days) and subsequent recovery (average 17 days post nadir). The demonstrated recovery post nadir for CLR 131 compared favorably to other similar radiotherapeutic drugs, such as Bexxar, which requires on average 90 days for recovery post nadir.

"These results showed excellent safety with limited off-target effects and improved tolerability compared to our single bolus dosing. With the overall activity observed with CLR 131 to date and efficacy signals across all doses and especially at the fractionated dosing level of 37.5 mCi/m^2, we remain optimistic about the potential for continued enhancement of efficacy and safety with fractionated dosing," said Jim Caruso, president and CEO of Cellectar. "We anticipate announcing additional data in the coming weeks in patients receiving single bolus and fractionated dosing from our Phase 2 CLOVER-1 trial, in which we have enrolled approximately 50 patients."

A copy of the presentation deck can be accessed on the Posters and Publications section of the Cellectar website.

About the Phase 2 CLOVER-1 Trial
CLOVER-1 is a Phase 2 study of CLR 131 being conducted in approximately 10 leading cancer centers in the United States in patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being studied in the trial include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL).

The study will enroll up to 80 patients. Its primary endpoint is clinical benefit response (CBR), with additional endpoints of overall response rate (ORR), progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a fractionated dose of 37.5mCi/m^2 of CLR 131 administered in two 30-minute infusions of 18.75mCi/m^2 of CLR 131 administered on day 1 and day 7 (± 1), with the option for a second dose cycle approximately 75-180 days later. The company expects to report topline data in 2019.

Cellectar was awarded approximately $2 million in non-dilutive grant funding from the National Cancer Institute to help fund the trial. More information about the trial, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

About the Phase 1 R/R MM Trial
The Phase 1 multicenter, open-label, dose-escalation study is designed to evaluate the safety and tolerability of CLR 131 administered as a 30-minute IV infusion, either as a single bolus dose or as two fractionated doses, in patients with R/R MM. All doses to date have been deemed safe and well tolerated by an independent Data Monitoring Committee (DMC). Based on the data and the recommendation of the DMC, the Company is enrolling a Cohort 7 where patients will receive 40mCi/m^2 fractionated dose of CLR 131.

About CLR 131
CLR 131 is a small-molecule, targeted Phospholipid Drug Conjugate™ (PDC) designed to deliver cytotoxic radiation directly to cancer cells, while limiting exposure to healthy cells. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-cell lymphomas, and two Phase 1 dose-escalating clinical studies, one in multiple myeloma and one in pediatric solid tumors and lymphoma. CLR 131 was granted Orphan Drug designation for the treatment of multiple myeloma by both the U.S. and the European Commission, and was granted U.S. Orphan Drug and Rare Pediatric Disease designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company is developing proprietary drugs independently and through research and development (R&D) collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop PDCs that specifically target cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's lead PDC therapeutic, CLR 131, is currently in three clinical studies – a Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed/refractory (R/R) B-cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with R/R multiple myeloma (MM) and a Phase 1 study in pediatric solid tumors and lymphoma.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets.

For more information, please visit www.cellectar.com or join the conversation by liking and following us on our social media channels: Twitter, LinkedIn, and Facebook.

Forward-Looking Statement Disclaimer

This news release contains forward-looking statements. You can identify these statements by our use of words such as "may", "expect", "believe", "anticipate", "intend", "could", "estimate", "continue", "plans", or their negatives or cognates. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the disruptions at our sole source supplier of CLR 131, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, the volatile market for priority review vouchers, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2018 and Form 10-Q for the quarters ended March 31, 2019, June 30, 2019 and September 30, 2019. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

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