

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): **September 30, 2019**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(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 September 30, 2019, we issued a press release announcing that Jarrod Longcor, our chief business officer, presented data from the diffuse large B cell lymphoma (DLBCL) cohort in our Phase 2 CLOVER-1 study of CLR 131 in relapsed or refractory select B-cell malignancies at the European Society for Medical Oncology (ESMO) Congress 2019 being held from September 27 – October 1, 2019 in Barcelona, Spain.. 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

<u>Number</u>	<u>Title</u>
99.1	<u>Press release dated September 30, 2019, titled “Collectar Presents Data from DLBCL Cohort of its Phase 2 CLOVER-1 Study at the European Society for Medical Oncology (ESMO) Congress”</u>

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: September 30, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Cellecstar Presents Data from DLBCL Cohort of its Phase 2 CLOVER-1 Study at the European Society for Medical Oncology (ESMO) Congress

Data showed durable clinical responses, including a 33% overall response rate (ORR) and 16.6% complete response (CR)

FLORHAM PARK, N.J., September 30, 2019 – **Cellecstar 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 Jarrod Longcor, chief business officer of Cellecstar, presented data from the diffuse large B cell lymphoma (DLBCL) cohort in the company's Phase 2 CLOVER-1 study of CLR 131 in relapsed or refractory select B-cell malignancies at the European Society for Medical Oncology (ESMO) Congress 2019 being held from September 27 – October 1, 2019 in Barcelona, Spain.

The oral presentation, entitled: "*Interim Evaluation of a Targeted Radiotherapeutic, CLR 131, in Relapsed/Refractory Diffuse Large B-Cell Lymphoma Patients (R/R DLBCL)*," featured data from 6 subjects who received a single 30-minute intravenous (IV) dose of 25mCi/m^2 of CLR 131. Data showed durable responses, including a 33% overall response rate (ORR), a 16.6% complete response rate (CR) and a 50% clinical benefit rate (CBR). All patients enrolled in the study received an average of 3 prior lines of systemic therapy, 5 of 6 patients were refractory to at least one prior line of therapy. Importantly, CLR 131 showed activity against both germinal center and activated DLBCL. In a patient for whom cytogenetics was available, CLR 131 showed activity against c-Myc and BCL-2 mutation (single & dual-hit) positive patients. As required by the Lugano Criteria for Response, the patient who experienced a CR had a total reduction in tumor volume of greater than 99% and continues to be a CR at 510+ days post dosing. This patient was refractory to two prior treatment lines, which included the combination regimen RICE.

Analysis of dosing showed that the disease control rate and progression free survival were markedly improved in patients receiving a dosing ratio of 1.2% or greater (drug to tumor volume) versus those receiving below a 1.2% dosing ratio. Finally, the most frequent adverse events (AE) in DLBCL patients were consistent with prior studies of CLR 131; the majority of AEs being hematologic in nature and predominately Grades 1 and 2.

"The data presented show an encouraging overall response rate including a complete response at the time of the interim assessment after a single 30-minute IV dose of 25mCi/m^2 of CLR 131. We remain optimistic that CLR 131 has the potential to provide a meaningful treatment option for a variety of lymphoma patients and look forward to reporting additional data from this Phase 2 CLOVER-1 study in 2019," said James Caruso, president and CEO of Cellecstar. "The study remains ongoing and, based on this cohort and additional data from an ongoing dose escalation Phase 1 study, patients in the Phase 2 CLOVER-1 study are now receiving a higher 37.50 mCi/m^2 fractionated dose administered in two 30-minute infusions of 18.75mCi/m^2 ."

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 37.575mCi/m² of CLR 131 administered in two 30-minute infusions of 18.75mCi/m² of CLR 131 administered on day 1 and day 8, with the option for a second dose cycle approximately 75-180 days later. The company expects to report topline data in 2019.

Collectar 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 CLR 131

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic Phospholipid Drug ConjugateTM (PDC) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is the company's lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma as well as orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In addition to the ongoing Phase 1 dose-escalation study and the Phase 2 (CLOVER-1) trial, the company recently initiated a Phase 1 open-label, dose-escalating study in pediatric solid tumors and lymphoma to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

About Collectar Biosciences, Inc.

Collectar 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.collectar.com.

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 and June 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.

Contacts**Investors:**

Monique Kosse
Managing Director
LifeSci Advisors
646-915-3820
monique@lifesciadvisors.com
