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): **May 21, 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 August 20, 2019	CLRBW	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 7.01 REGULATION FD DISCLOSURE

On May 21, 2019, we issued a press releaseannouncing that initial results from the third cohort of our ongoing Phase 2 CLOVER-1 study of CLR 131 has exceeded its pre-specified performance criteria. 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 May 21, 2019, titled "Cellectar Expands Third Cohort of its Phase 2 CLOVER-1 Study of CLR 131"

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: May 21, 2019

CELLECTAR BIOSCIENCES, INC.

By: */s/ Charles T. Bernhardt*
Name: Charles T. Bernhardt
Title: Interim Chief Financial Officer

Exhibit 99.1

Cellectar Expands Third Cohort of its Phase 2 CLOVER-1 Study of CLR 131

Response rate exceeded pre-specified value; top-line results of Phase 2 study expected in 2019

FLORHAM PARK, N.J., May 21, 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 that initial results from the third cohort of its ongoing Phase 2 CLOVER-1 study of CLR 131 have exceeded its pre-specified performance criteria. As a result, the Company will expand the number of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL) and marginal zone lymphoma (MZL) patients it will enroll in the cohort. The company continues to expect to report top-line data from the Phase 2 CLOVER-1 study in 2019.

“Initial results from our Phase 2 CLOVER-1 study have been very encouraging and we are excited to be able to expand patient enrollment,” stated James Caruso, president and chief executive officer of Cellectar Biosciences. “With the proceeds from the recently announced financing, we now have a cash runway through the conclusion of 2020, allowing us to deliver key anticipated milestones for CLR 131 in three ongoing clinical trials, including the conclusion of and top-line data from our ongoing Phase 2 CLOVER-1 trial in relapse/refractory select B-Cell malignancies, our ongoing Phase 1 dose-escalating trial in relapsed/refractory multiple myeloma, and our recently initiated Phase 1 dose-escalating trial in children and adolescents with select solid tumors, lymphoma, and malignant brain tumors.”

The company previously announced positive top-line data from two cohorts of the ongoing Phase 2 CLOVER-1 trial. In the relapsed/refractory diffuse large b-cell lymphoma (DLBCL) cohort, CLR 131 demonstrated a 33% overall response rate as a fourth line systemic treatment; and in the relapsed/refractory multiple myeloma (MM) cohort, CLR 131 demonstrated a 30% overall response rate as the seventh line systemic treatment on average. Patients in both of these cohorts received a single 30-minute infusion of 25mCi/m^2 of CLR 131. The company continues to enroll patients in both cohorts and patients are now receiving 37.575mCi/m^2 of CLR 131 administered in two 30-minute infusions of 18.75mCi/m^2. The company expects to announce top-line data from the Phase 2 CLOVER-1 trial in 2019.

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's 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/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 8, with the option for a second dose cycle approximately 75-180 days later.

In addition to receiving the two fractionated doses of CLR 131, MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. 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 CLR 131
CLR 131 is a small-molecule, cancer-targeting radiotherapeutic 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. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted 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 Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery, development, and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage its PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, Cellectar seeks to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and to broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 2 clinical study (CLOVER-1) in R/R MM and select B-cell malignancies, as well as a dose escalation Phase 1 study in patients with R/R MM. The company has initiated a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma.

Cellectar'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.

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 quarter ended March 31, 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

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