UNITED STATESSECURITIES 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): **July 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 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 July 9, 2019, we issued a press release announcing the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for CLR 131 in relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL). 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 July 9, 2019, titled "Cellectar Receives FDA Fast Track Designation for CLR 131 in Diffuse Large B-Cell Lymphoma"

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: July 9, 2019

CELLECTAR BIOSCIENCES, INC.

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

Exhibit 99.1

Cellectar Receives FDA Fast Track Designation for CLR 131 in Diffuse Large B-Cell Lymphoma

FLORHAM PARK, N.J., July 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 U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for CLR 131 in relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL). CLR 131 is the company's small-molecule, cancer-targeting radiotherapeutic Phospholipid Drug Conjugate™ (PDC™) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in Cellectar's ongoing Phase 2 CLOVER-1 clinical study in patients with relapsed or refractory select B-Cell lymphomas.

"We are pleased to receive FDA's Fast Track Designation for CLR 131. This designation supports our efforts to more rapidly provide a new therapeutic option for patients with relapsed or refractory DLBCL, a disease that typically has a very poor prognosis and low rates of survival," said James Caruso, president and CEO of Cellectar. "As announced last year, data from the DLBCL cohort in our ongoing CLOVER-1 trial showed an encouraging 33% overall response rate at the time of the interim assessment. Patients prior to the interim assessment received a single 25.0 mCi/m^2 dose of CLR 131. Dosing in the Phase 2 CLOVER-1 study has increased, and patients are now receiving 37.50 mCi/m^2 fractionated in two administrations of CLR 131. We are optimistic that CLR 131 has the potential to provide a meaningful treatment option for these patients and look forward to additional data in 2019."

Fast Track Designation
Fast Track Designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the Fast Track Designation provision is to help facilitate development and expedite the review and potential approval of drugs to treat serious and life-threatening conditions.

Sponsors of drugs that receive Fast Track Designation have the opportunity for more frequent interactions with the FDA review team throughout the development program. These can include meetings to discuss study design, data required to support approval, or other aspects of the clinical program. Additionally, products that have been granted Fast Track Designation may be eligible for priority review of a New Drug Application (NDA) and the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application (Rolling Review).

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 8, 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 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, and was granted Orphan Drug and Rare Pediatric Disease 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 plans to develop 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. Our PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and we plan 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 refractory/relapsing (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.

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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