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

ITEM 7.01 REGULATION FD DISCLOSURE

On May 13, 2019, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for CLR 131 in fourth line or later relapse/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 May 13, 2019, titled "Cellectar Receives FDA Fast Track Designation for CLR 131 in Relapsed or Refractory Multiple Myeloma"

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 13, 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 Relapsed or Refractory Multiple Myeloma

Designation could accelerate CLR 131 development and underscores the need for new treatments

FLORHAM PARK, N.J., May 13, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for CLR 131 in fourth line or later relapse/refractory multiple myeloma. CLR 131 is the company's small-molecule 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 CLOVER-1 Phase 2 clinical study in patients with relapsed or refractory multiple myeloma and other select B-Cell lymphomas.

"Fast Track Designation furthers our efforts to expeditiously develop CLR 131 as a new, innovative therapy for patients with relapse/refractory multiple myeloma", said James Caruso, president and CEO of Cellectar. "Patients with third line or later relapsed/refractory multiple myeloma have a poor prognosis and low rates of survival as a result of limited effective treatment options. Based on data in the initial patient cohort from our ongoing CLOVER-1 trial where patients showed a 30% response rate after receiving a single 25.0 mCi/m^2 dose as a seventh line of therapy on average, we are optimistic that CLR 131 has the potential to provide a meaningful treatment option for these patients."

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 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 interactions may 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'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 15.625 mCi/m^2 dose 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's seeks to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and 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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