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): **August 14, 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 August 14, 2019, we issued a press release announcing that we have successfully completed the first cohort of malignant brain tumor patients in our ongoing Phase 1 trial of CLR 131 in children and adolescents with select solid tumors, lymphoma, and malignant brain tumors, including relapsed or refractory neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. 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 August 14, 2019, titled "CLR 131 Advances to Second Malignant Brain Tumor Cohort of Ongoing Pediatric Phase 1 Study"

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: August 14, 2019

CELLECTAR BIOSCIENCES, INC.

By *<u>/s/ Charles T. Bernhardt</u>*
Name: Charles T. Bernhardt
Interim Chief Financial Officer

Exhibit 99.1

CLR 131 Advances to Second Malignant Brain Tumor Cohort of Ongoing Pediatric Phase 1 Study

Independent Data Monitoring Committee recommends the study continue to higher dose after first dose deemed safe and tolerated

FLORHAM PARK, N.J., Aug. 14, 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 it has successfully completed the first cohort of malignant brain tumor patients in its ongoing Phase 1 trial of CLR 131 in children and adolescents with select solid tumors, lymphoma, and malignant brain tumors, including relapsed or refractory neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. The independent Data Monitoring Committee determined the 15mCi/m^2 bolus dose to be safe and tolerated and recommended the company progress to a second cohort utilizing a 30 mCi/m^2 bolus dose of CLR 131.

"CLR 131 continues to advance through its Pediatric Phase 1 dose escalation study and we are encouraged by our pace of progress," said James Caruso, President and CEO of Cellectar. "Pediatric patients with primary metastatic or relapsed solid tumors have very poor prognosis even with standard, highly toxic multimodality therapies and salvage regimens. We look forward to exploring the next dose and having additional safety data from this study later this year."

About the Phase 1 Pediatric Study of CLR 131

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study designed to evaluate the safety and tolerability, toxicity, pharmacokinetics, biodistribution and efficacy of single and fractionated intravenous administrations of CLR 131 in up to 30 children and adolescents with select solid tumors, lymphoma, and malignant brain tumors, including relapsed or refractory malignant brain cancer, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. Secondary objectives of the study are to identify doses at which preliminary anti-tumor activity occurs and to assess drug accumulation within the different tumor types.

The first cohort in malignant brain tumor patients received a 15mCi/m^2 bolus dose of CLR 131 and based on results, the company is progressing to a second cohort of patients, who will receive a higher 30mCi/m^2 bolus dose of CLR 131. The company will progress to additional cohorts at higher fractionated doses, if the dose in the second cohort is determined to be safe and tolerated. The multi-center study is being conducted at well-respected U.S. and international sites. Further details about the trial can be found at clinicaltrials.gov using the identifier number NCT03478462.

Rare Pediatric Drug Designation
CLR 131 has been granted Rare Pediatric Drug Designation (RPDD) for four separate pediatric disease indications: neuroblastoma, rhabdomyosarcoma, osteosarcoma and Ewing's sarcoma. Should CLR 131 be approved by the FDA in any one of these indications, the RPDD may enable Cellectar to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review designation for a future NDA or BLA submission, which could reduce the FDA review time from twelve months to eight months. Currently these vouchers can also be transferred or sold to another entity. Since 2017, six priority review vouchers were sold for between $80 and $150 million each.

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. 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 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 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 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.

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