CELLECTAR BIOSCIENCES, INC.

FORM 8-K
(Current report filing)

Filed 12/14/17 for the Period Ending 12/14/17

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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: December 14, 2017
(*Date of earliest event reported*)

CELLECTAR BIOSCIENCES, INC.
(*Exact name of registrant as specified in its charter*)

Delaware	**1-36598**	**04-3321804**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification Number)*

3301 Agriculture Drive, Madison, Wisconsin 53716
(*Address of principal executive offices*)

(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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§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. ☐

ITEM 7.01 REGULATION FD DISCLOSURE

On December 14, 2017, we issued a press release announcing that we have filed an Investigational New Drug (IND) application with the Division of Oncology at the U.S. Food and Drug Administration (FDA) for a proposed Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
99.1	Press release dated December 14, 2017, titled "Cellectar Files IND for Phase 1 Trial of CLR 131 in Pediatric Cancers"

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: December 14, 2017

CELLECTAR BIOSCIENCES, INC.

By: */s/ John P. Hamill*
Name: John P. Hamill
Title: Interim Chief Financial Officer

Exhibit 99.1

Cellectar Files IND for Phase 1 Trial of CLR 131 in Pediatric Cancers

Madison, Wis., December 14, 2017 – 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 announces that the company has filed an Investigational New Drug (IND) application with the Division of Oncology at the U.S. Food and Drug Administration (FDA) for a proposed Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers.

The proposed Phase 1 clinical trial of CLR 131 is an open-label, sequential-group, dose-escalation study 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. Secondary objectives of the study are to identify the recommended Phase 2 dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents.

The study will be initiated with the pediatric oncologists and Nuclear Medicine/Radiology Group at The University of Wisconsin Carbone Cancer Center.

"The University of Wisconsin group makes an ideal partner for the development of CLR 131 in pediatric cancers because of the quality of their investigators, prominence as a leading U.S. pediatric treatment center and extensive experience with beta-emitting radioisotope therapies. Together, our hope is to bring new and effective treatment options for children battling life-threatening cancers," stated John Friend, M.D., chief medical officer of Cellectar Biosciences.

CLR 131 is an investigational phospholipid drug conjugate (PDC), radioiodinated cancer therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ethers (PLEs) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues.

Dr. Otto and co-workers of The University of Wisconsin have demonstrated uptake of CLR 131 and other fluorescently and isotopically tagged PDCs across a wide range of childhood solid cancer cell lines including, Ewing sarcoma, rhabdomyosarcoma, pediatric brain tumors such as high-grade gliomas, medulloblastoma and atypical teratoid rhabdoid tumor. In subsequent testing in mouse xenograft models of neuroblastoma, Ewing sarcoma, rhabdomyosarcoma and osteosarcoma, CLR 131 provided significant benefits on tumor growth rates and survival.

"We are particularly pleased to advance CLR 131 in this refractory pediatric patient population as currently most of these children have a very poor prognosis for survival. We are highly encouraged by the preclinical data in pediatric cancers that have shown CLR 131 to have meaningful benefit on tumor growth rates and survival," stated Jim Caruso, president and chief executive officer of Cellectar Biosciences.

About CLR 131
CLR 131 is an investigational compound under development for a range of orphan designated cancers. It is currently being evaluated as a single-dose treatment in a Phase I clinical trial in patients with relapsed/refractory (R/R) multiple myeloma (MM) as well as in a Phase II clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. Based upon preclinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating solid and hematological tumors and may provide patients with therapeutic benefits, including overall survival, an improvement in progression-free survival, surrogate efficacy marker response rate, and overall quality of life. CLR 131 utilizes the company's patented phospholipid ether drug conjugate (PDC) tumor targeting delivery platform to deliver a cytotoxic radioisotope, iodine-131, directly to tumor cells. The FDA has granted Cellectar an orphan drug designation for CLR 131 in the treatment of MM.

About Phospholipid Drug Conjugates (PDCs)
Cellectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). The company deliberately designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate both therapeutic and diagnostic applications. The basis for selective tumor targeting of our PDC compounds lies in the differences between the plasma membranes of cancer cells compared to those of normal cells. Cancer cell membranes are highly enriched in lipid rafts, which are glycolipoprotein microdomains of the plasma membrane of cells that contain high concentrations of cholesterol and sphingolipids, and serve to organize cell surface and intracellular signaling molecules. PDCs have been tested in more than 80 different xenograft models of cancer.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is developing phospholipid drug conjugates (PDCs) designed to provide cancer targeted delivery of diverse oncologic payloads to a broad range of cancers and cancer stem cells. Cellectar's PDC platform is based on the company's proprietary phospholipid ether analogs. These novel small-molecules have demonstrated highly selective uptake and retention in a broad range of cancers, even sites of metastases. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 has been designated as an orphan drug by the U.S. FDA and is currently being evaluated in a Phase 1 clinical study in patients with relapsed or refractory multiple myeloma and a Phase 2 clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing proprietary PDCs for targeted delivery of chemotherapeutics and has several preclinical stage product candidates, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. 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 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, 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, 2016. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

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