**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report: July 9, 2018
(*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 July 9, 2018, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to CLR 131, our lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of Ewing's sarcoma, a rare pediatric cancer. 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, 2018, titled "Cellectar's CLR 131 Receives FDA Orphan Drug Designation for Treatment of Ewing's Sarcoma" |

**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, 2018

**CELLECTAR BIOSCIENCES, INC.**

By: */s/ Brian M. Posner*
Name: Brian M. Posner
Title: Chief Financial Officer

**Exhibit 99.1**

# Cellectar's CLR 131 Receives FDA Orphan Drug Designation for Treatment of Ewing's Sarcoma

**MADISON, Wis. (July 9, 2018)** – Cellectar Biosciences (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, announces that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to CLR 131, the company's lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of Ewing's sarcoma, a rare pediatric cancer.

"Ewing's sarcoma is the second most common bone malignancy among children and adolescents and there are limited treatment options for patients who relapse or become refractive to therapy," said John Friend, M.D., chief medical officer of Cellectar. "The ODD for Ewing's sarcoma represents another important milestone for our CLR 131 pediatric program as we work to bring new options to patients suffering from rare cancers."

The FDA grants orphan drug designation to therapies targeted at conditions that affect fewer than 200,000 people in the United States. The designation provides seven-year market exclusivity, increased engagement and assistance from the FDA, tax credits for certain research, research grants and a waiver of the New Drug Application user fee. In 2018 the FDA also granted CLR 131 orphan drug and rare pediatric disease designations for the treatment of neuroblastoma and rhabdomyosarcoma.

Cellectar is currently initiating a Phase 1 clinical study evaluating CLR 131 for the potential treatment of pediatric patients with Ewing's sarcoma, rhabdomyosarcoma, osteosarcoma, neuroblastoma, high grade glioma and lymphomas. Cellectar has received clearance from the FDA to proceed with an accelerated Phase 1 trial, designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of CLR 131 in pediatric patients with these cancer types. Further details about the trial can be found at clinicaltrials.gov using the identifier number NCT03478462.

**About Ewing's Sarcoma**

Ewing's sarcoma is the second most common bone malignancy among children and adolescents. According to a study published in the Journal of Hematology/Oncology, the incidence is about 3 cases per 1 million per year in children younger than age 20. Despite the favorable prognosis, an American Cancer Society study showed that approximately 30-40% of patients develop metastases or local recurrence, and the long-term survival rate for refractory or recurrent disease is only 22-24%. The relapsed and refractory statistics underscore the need for new treatment options.

**About CLR 131**
CLR 131 is Cellectar's investigational radioiodinated PDC therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131, is in a Phase 2 clinical study in relapsed or refractory (R/R) MM and a range of B-cell malignancies and a Phase 1 clinical study in patients with (R/R) MM exploring fractionated dosing. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer.

**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 our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is 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 1 clinical study in patients with relapsed or refractory (R/R) MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

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, 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, 2017. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

**CONTACT:**
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