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): **January 6, 2020**

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 April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 7.01 REGULATION FD DISCLOSURE

On January 6, 2020, we issued a press releaseannouncing that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to CLR 131 in Lymphoplasmacytic Lymphoma (LPL). 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 January 6, 2020, titled "Cellectar Receives Orphan Drug Designation for CLR 131 in Lymphoplasmacytic Lymphoma (LPL)"

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: January 6, 2020

CELLECTAR BIOSCIENCES, INC.

By: */s/ Dov Elefant*
Name: Dov Elefant
Title: Chief Financial Officer

Exhibit 99.1

Cellectar Receives Orphan Drug Designation for CLR 131 in Lymphoplasmacytic Lymphoma (LPL)

FLORHAM PARK, N.J., January 6, 2020 -- 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) Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to CLR 131 in Lymphoplasmacytic Lymphoma (LPL). CLR 131 is the company's lead Phospholipid Drug Conjugate ™ (PDC) product candidate currently in a Phase 2 clinical study in relapsed or refractory select B-cell lymphomas, including Lymphoplasmacytic Lymphoma (LPL).

"The orphan designation from the FDA for LPL represents the sixth for CLR 131 and underscores Cellectar's commitment to develop therapies for rare cancers with limited treatment options and high unmet need," stated James Caruso, president and CEO of Cellectar Biosciences. "CLR 131 has demonstrated encouraging results in our ongoing Phase 2 CLOVER-1 trial in select B-cell lymphomas, which includes LPL patients. We look forward to sharing Phase 2 LPL clinical data in the near term."

The FDA grants ODD to therapies targeting conditions that affect fewer than 200,000 people in the U.S. The designation provides seven years of 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. CLR 131 has previously been granted Orphan Drug designation for the treatment of multiple myeloma by both the U.S. and the European Commission and Rare Pediatric Disease and Orphan Drug designations for the treatments of neuroblastoma, rhabdomyosarcoma, osteosarcoma, Ewing's sarcoma.

About Lymphoplasmacytic Lymphoma (LPL)

LPL is a rare type of non-Hodgkin's lymphoma that develops slowly and affects mostly older adults. The average age at diagnosis is 60. Lymphomas are cancers of the lymph system, a part of the immune system that helps to fight off infections. In lymphoma, white blood cells, either B lymphocytes or T lymphocytes, grow out of control because of a mutation. In LPL, abnormal B lymphocytes reproduce in the bone marrow and displace healthy blood cells, compromising the body's immune system and potentially resulting in anemia, neutropenia, or thrombocytopenia.

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 7 (± 1), with the option for a second dose cycle approximately 75-180 days later.

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 by both the U.S. and the European Commission, and was granted U.S. Orphan Drug and Rare Pediatric Disease designations 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 is developing proprietary drugs independently and through research and development 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. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's lead PDC therapeutic, CLR 131, is currently in three clinical studies - one 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 lymphomas.

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 or join the conversation by liking and following us on the company's social media channels: Twitter, LinkedIn, and Facebook.

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 studies, 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, June 30, 2019 and September 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
212-915-3820
monique@lifesciadvisors.com