

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): **July 21, 2020**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(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 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))

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

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 21, 2020, we issued a press release announcing a poster presentation at the upcoming American Association of Cancer Research (AACR) annual meeting being held virtually on August 17-19, 2020. 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
<u>99.1</u>	<u>Press release dated July 21, 2020, titled “Cellecrar Announces Poster Presentation of Clinical Data at the American Association of Cancer Research (AACR) Annual Meeting”</u>

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 21, 2020

CELLECTAR BIOSCIENCES, INC.

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

Cellectar Announces Poster Presentation of Clinical Data at the American Association of Cancer Research (AACR) Annual Meeting

Data highlight initial results of 100% overall response rate from ongoing Phase 2 trial in Relapsed or Refractory lymphoplasmacytic lymphoma (LPL)/Waldenstrom's Macroglobulinemia (WM)

FLORHAM PARK, N.J., July 21, 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 a poster presentation at the upcoming American Association of Cancer Research (AACR) annual meeting being held virtually on August 17-19, 2020.

Poster presentation details:

Poster Title	CLR 131 Demonstrates 100% Overall Response Rate in Relapsed or Refractory Lymphoplasmacytic Lymphoma (LPL)/Waldenstrom's Macroglobulinemia (WM): Initial Results from Ongoing Phase 2 trial, CLOVER-1 Study
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A copy of the presentation materials can be accessed on the [Events and Presentations](#) section of the Cellectar website once the presentation has concluded.

About CLR 131

CLR 131 is a small-molecule Phospholipid Drug Conjugate™ designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while limiting exposure to healthy cells unlike many traditional on-market treatment options. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-cell lymphomas, and a Phase 1 dose-escalating clinical study in pediatric solid tumors and lymphomas. The company recently completed a Phase 1 dose-escalation clinical study in r/r multiple myeloma. The FDA granted CLR 131 Fast Track Designation for both r/r multiple myeloma and r/r diffuse large b-cell lymphoma and Orphan Drug Designation (ODD) for the treatment of multiple myeloma, lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 was also granted Rare Pediatric Disease Designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Most recently, the European Commission granted an ODD for r/r multiple myeloma.

About the Phase 2 CLOVER-1 Study

CLOVER-1 is a Phase 2 study of CLR 131 being conducted in 10 leading cancer centers in the United States in patients with relapsed/refractory B-cell hematologic cancers. The hematologic cancers studied include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL).

The study can enroll up to 80 patients with its primary endpoint being clinical benefit response (CBR), which is defined as the proportion of MM patients following infusion of CLR 131 with stringent complete response, complete response, very good partial response, partial response and stable disease per International Myeloma Working Group criteria, or the proportion of lymphomas patients (CLL/SLL, LPL, MZL, MCL, and DLBCL) following infusion of CLR 131 with CR, PR and SD per the Lugano classification CT-based response criteria or International Waldenström's Macroglobulinemia Society criteria or the International Chronic Lymphocytic Leukemia criteria. Additional endpoints include overall response rate (ORR), progression free survival (PFS), median overall survival (OS) and other markers of efficacy. Patients were treated with three different doses (<60mCi single cycle, ≥60mCi single cycle and ≥60 mCi multi-cycle total body dose).

The CLOVER-1 Phase 2 study completed the Part A dose-exploration portion conducted in relapsed/refractory (r/r) B-cell malignancies and is now enrolling in the Part B expansion cohorts in relapsed/refractory (r/r) multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenström's macroglobulinemia (LPL/WM). Part B is evaluating the two cycle dosing of CLR 131 in additional patients. Each cycle is defined as two doses provided 14 days apart (+/- 1 day). Cycle 2 shall be given 8-weeks post the initial infusion. Additional cycles can be considered following an additional 8-week period. The Part A portion of the study met its primary and secondary endpoints with detailed data being announced on February 19, 2020.

Collectar was awarded approximately \$2 million in non-dilutive grant funding from the National Cancer Institute to help fund the study. More information about the study, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

About Collectar Biosciences, Inc.

Collectar 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 two clinical studies. The CLOVER-1 Phase 2 study completed the Part A dose-exploration portion, conducted in relapsed/refractory (r/r) B-cell malignancies, and is now enrolling in the Part B expansion cohorts evaluating a two cycle dosing regimen that provides approximately 100mCi total body dose of CLR 131 in relapsed/refractory (r/r) multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenström's macroglobulinemia (LPL/WM). The data from the Part A portion was announced on February 19, 2020. The company is also conducting a two-part Phase 1 dose-escalation with expansion arms in pediatric solid tumors and lymphomas.

The company's product pipeline includes one preclinical PDC chemotherapeutic program (CLR 1900) and multiple partnered PDC assets.

For more information, please visit www.collectar.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 including our expectations of the impact of the recent COVID-19 pandemic. 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, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for CLR 131, 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, 2019 and our Form 10-Q for the quarter ended March 31, 2020. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements. 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
