

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 17, 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 August 17, 2020, we issued a press release announcing that Jarrod Longcor, our chief business officer, presented a poster at the American Association of Cancer Research (AACR) VIRTUAL MEETING: ADVANCES IN MALIGNANT LYMPHOMA being held 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 August 17, 2020, titled "Collectar Presents Poster at the AACR VIRTUAL MEETING: ADVANCES IN MALIGNANT LYMPHOMA"</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: August 17, 2020

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer

Collectar Presents Poster at the AACR VIRTUAL MEETING: ADVANCES IN MALIGNANT LYMPHOMA

Poster highlights the Phase 2a study data in relapsed or refractory lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM)

Interim results show 100% overall response rate and a 75% major response rate

FLORHAM PARK, N.J., August 17, 2020 -- Collectar 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 Jarrod Longcor, chief business officer of Collectar, presented a poster at the American Association of Cancer Research (AACR) VIRTUAL MEETING: ADVANCES IN MALIGNANT LYMPHOMA being held August 17-19, 2020. The abstract was submitted April 2, 2020.

The poster, entitled: “*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-I Study*” reviews data from four patients enrolled in the Phase 2a portion of the ongoing Phase 2 CLOVER-I study of CLR 131. The presentation featured efficacy and safety data highlighting;

- 100% overall response rate,
- 25% complete response rate,
- 75% major response rate (patients achieving partial response or better), and
- Mean duration of response exceeding 17 months (8.4 – 31.7 months); duration of response continues to increase for all patients

The safety profile in these highly pretreated patients with relapsed or refractory LPL/ WM was predictable and adverse events were similar to those observed in previous CLR 131 clinical studies in B-cell malignancies. The predominate treatment emergent adverse event remains cytopenias with all patients recovering. Importantly, no patients experienced adverse events that are frequently associated with treatments prescribed for LPL/WM patients such as atrial fibrillation, peripheral neuropathy, ocular toxicities, bleeding events, liver toxicities, renal toxicities or other “off-target” effects.

“CLR 131's ability to treat various LPL/WM patients including those who do not respond to or are intolerant of ibrutinib is a potentially important therapeutic advance. The potential for patients to have a long term drug treatment holiday whereby there is no requirement for taking a pill once or twice a day for years is clinically meaningful,” said study investigator Sikander Ailawadhi, M.D., Division of Hematology/Oncology, Department of Internal Medicine, Mayo Clinic, Jacksonville, Florida.

“The overall product profile and achievement of a complete response as a monotherapy, along with the extended duration of responses in patients that are refractory to at least one prior therapy and have also received multiple lines of treatment is highly encouraging,” said Jarrod Longcor. “These patients currently have limited treatment options and CLR 131 may represent an important potentially disease modifying improvement in the LPL/WM treatment paradigm. We plan to initiate our pivotal study and potentially report additional LPL/WM data later this year.”

There is currently only one approved drug for the treatment of relapsed or refractory LPL/WM. In May of this year, the U.S. Food and Drug Administration granted Fast Track Designation for CLR 131 in treatment of relapsed or refractory LPL/WM. The company currently continues to enroll patients in the Phase 2b portion of the CLOVER-1 study and plans to initiate a pivotal study in LPL/WM in the fourth quarter of 2020.

About CLOVER 1

The Phase 2 CLOVER-1 study is an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies. 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 r/r multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM). Patients with LPL/WM must have received at least two prior treatment regimens, unless ineligible to receive standard agents, and have measurable disease, as defined by either a nodal lesion of > 15 mm, an extranodal lesion of > 10 mm, or measurable IgM. Prior external beam radiation therapy was allowed. The median age of the four LPL/WM patients enrolled in the study was 70 (range 54-81) and included 2 females and 2 males who had a median of two prior regimens (range 1-5). CLR 131 was administered intravenously, up to 30 minutes at total body doses (TBD) of <50mCi, ~50 mCi, and ~75mCi.

A copy of the presentation materials can be accessed on the [Events and Presentations](#) section of the Collectar website once the presentations conclude.

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. Earlier this year, the European Commission granted an ODD for r/r multiple myeloma and most recently, the U.S. Food and Drug Administration granted Fast Track Designation for CLR 131 in lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM) in patients having received two prior treatment regimens or more.

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 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 Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

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 quarters ended March 31, 2020 and June 30, 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.

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