

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 9, 2020**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in 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 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 9, 2020, we issued a press release announcing that we will host a Clinical Data Call on Wednesday, February 19, 2020 at 10:30 am Eastern Time. 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 January 9, 2020, titled “Collectar Biosciences to Host a CLR 131 Clinical Data Call with Its Phase 2 Lead Investigator on February 19, 2020”</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: January 9, 2020

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Collectar Biosciences to Host a CLR 131 Clinical Data Call with Its Phase 2 Lead Investigator on February 19, 2020

FLORHAM PARK, N.J., January 09, 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 it will host a Clinical Data Call on Wednesday, February 19, 2020 at 10:30 am Eastern Time.

Members of Collectar's senior management team and Dr. Sikander Ailawadhi, M.D., the lead investigator for the company's Phase 2 study, will provide additional clinical data, as well as an update and analysis of the CLR 131 Phase 1 and Phase 2 hematology focused trials. The team will also provide a summary of the data for patients with relapsed/refractory B-cell malignancies, including patients with multiple myeloma and select non-Hodgkins lymphoma. Additionally, the team will review the current treatment landscape and unmet medical need for treating patients with these cancers, and provide an overview of the market opportunity and its clinical development plan for CLR 131.

Sikander Ailawadhi, M.D., is an Associate Professor, Division of Hematology/Oncology at Mayo Clinic Florida and is the lead investigator for the company's Phase 2 CLOVER-1 trial of CLR 131 in patients with relapsed/refractory B-cell hematologic cancers. Dr. Ailawadhi was awarded the 2013 NCI CCITLA as an Assistant Professor of Medicine at the Norris Cancer Center, University of Southern California (USC), Los Angeles CA. Subsequently, he joined the Division of Hematology and Oncology at Mayo Clinic in Florida as a Senior Associate Consultant in order to pursue his career goal of clinical, translational and outcomes-based research in B-cell malignancies, especially plasma cell disorders.

Dial-In & Webcast Information

Domestic: 877-705-6003

International: 201-493-6725

Conference ID: 13697717

Webcast: <http://public.viavid.com/index.php?id=137456>

A replay of the call will be available on the [Events](#) section on the Investor Relations page of company's website following the live event.

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/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/m² of CLR 131 administered in two 30-minute infusions of 18.75mCi/m² of CLR 131 administered on day 1 and day 7 ($\pm$ 1), with the option for a second dose cycle approximately 75-180 days later.

Collectar 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 the Phase 1 R/R MM Trial

The Phase 1 multicenter, open-label, dose-escalation study is designed to evaluate the safety and tolerability of CLR 131 administered as a 30-minute IV infusion, either as a single bolus dose or as two fractionated doses, in patients with relapsed/refractory multiple myeloma. All doses to date have been deemed safe and well tolerated by an independent Data Monitoring Committee (DMC). Based on the data and the recommendation of the DMC, the company is enrolling a Cohort 7 where patients will receive 40mCi/m² fractionated dose of CLR 131.

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 designation for the treatment of lymphoplasmacytic lymphoma and was granted U.S. Orphan Drug and Rare Pediatric Disease designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

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 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

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