

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): **December 13, 2019**

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 December 13, 2019, we issued a press release announcing that Jarrod Longcor, our chief business officer, presented a poster at the AACR San Antonio Breast Cancer Symposium in San Antonio, TX.

On December 16, 2019, we issued a press release announcing summary data from 20 patients receiving a single dose of CLR 131 in its Phase 2 CLOVER-1 trial in select relapsed/refractory (RR) B-cell malignancies. Copies of the press releases are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
<u>99.1</u>	<u>Press release dated December 13, 2019, titled “Cellestar Presents Poster at the American Association for Cancer Research (AACR) San Antonio Breast Cancer Symposium”</u>
<u>99.2</u>	<u>Press release dated December 16, 2019, titled “Cellestar Announces Data From 20 Patients Receiving a Single 25mCi/M² Bolus Dose of CLR 131 in the Phase 2 CLOVER-1 Study”</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: December 16, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Cellestar Presents Poster at the American Association for Cancer Research (AACR) San Antonio Breast Cancer Symposium

Efficacy established in 4th class of molecules utilizing Phospholipid Ether Vehicle

FLORHAM PARK, N.J., December 13, 2019 -- Cellestar 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 Jarrod Longcor, chief business officer of Cellestar, presented a poster at the AACR San Antonio Breast Cancer Symposium in San Antonio, TX.

The poster, entitled: “*Preclinical evaluation of a novel phospholipid drug conjugate, CLR 2000045 with a combretastatin A-4 analogue for improved breast cancer therapy*,” featured data demonstrating potent *in vivo* activity in multiple animal models of breast cancer, including a model of triple negative breast cancer. Multiple doses of CLR 2000045 resulted in a statistically significant reduction in tumor volume ($p \leq 0.05$ and 0.01 respectively) and survival ($p \leq 0.05$ and 0.001 respectively) in the HCC70, triple negative breast cancer model as compared to vehicle control. In a separate study, the compound displayed comparable activity to paclitaxel in an initial screening model of metastatic breast cancer and the data showed that all doses of CLR 2000045 were well tolerated in both models.

“The data further demonstrate that PDCs are an exciting and novel class of targeted oncology agents with potential in a wide variety of tumor types,” said Jarrod Longcor, chief business officer of Cellestar. “We have validated targeted delivery to tumor cells and shown efficacy in multiple cancer types utilizing our phospholipid ether delivery vehicle with four separate classes of molecules. These data demonstrate the unique potential of our novel cancer targeting platform.”

About Phospholipid Drug Conjugates™

Cellestar's product candidates are built upon a patented delivery and retention platform that utilizes optimized phospholipid ether-drug conjugates (PDCs™) to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Cellestar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

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 (R&D) 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 – a 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 lymphoma.

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.collectar.com or join the conversation by liking and following us on our 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 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, 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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Cellecstar Announces Data From 20 Patients Receiving a Single 25mCi/M² Bolus Dose of CLR 131 in the Phase 2 CLOVER-1 Study

30% overall response rate seen with an average progression free survival of 4.5 months and an acceptable and expected safety profile

Additional data in patients receiving higher fractionated doses of CLR 131 anticipated in January

FLORHAM PARK, N.J., December 16, 2019 -- Cellecstar 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 summary data from 20 patients receiving a single dose of CLR 131 in its Phase 2 CLOVER-1 trial in select relapsed/refractory (RR) B-cell malignancies. The company had previously announced data from 10 multiple myeloma patients receiving a single dose of CLR 131 in February 2019, which showed a 30% overall response rate (ORR).

The Phase 2 CLOVER-1 study is designed to identify a safe and efficacious dose and regimen to be used in a pivotal study for select hematologic indications. The 20 evaluated patients, included 10 subjects with relapsed/refractory multiple myeloma, and 10 with relapsed/refractory B-cell lymphoma. The median age was 71 (range 52-82), including 7 females and 13 males, with a median of 6 prior systemic therapies for multiple myeloma and 4 for patients with lymphoma. Eight patients had prior autologous stem cell transplant therapy. Data from these 20 patients showed a 30% ORR, a 75% clinical benefit rate, an average progression free survival of 4.5 months and an acceptable and expected safety profile.

“The 30% ORR seen suggests that CLR 131 treatment at the single 25 mCi/m² bolus dose may have activity in these heavily pre-treated patients,” said James Caruso, president and CEO of Cellecstar Biosciences. “We recently presented data at ASH on 19 patients with relapsed, refractory multiple myeloma, which showed improved efficacy and safety with fractionated doses vs. the single bolus dose, and patients receiving a fractionated dose of 37.5mCi showed a 50% ORR. As background, recently approved drugs for this indication have demonstrated approximate ORRs of 25% in a similar patient population and up to 29% as a third line treatment. We plan to provide additional data in patients who are receiving higher fractionated doses of CLR 131 in January.”

The primary adverse events (AEs) seen were cytopenias, including thrombocytopenia, anemia, neutropenia, and decreased white blood cell count. The hematologic AEs were expected, manageable and followed a predictable timeline to nadir (average 49 days) and subsequent recovery (average 16 days post nadir). Patients with disease in the bone marrow experienced more cytopenias than did patients with no detectable disease in the bone marrow. All patients recovered from the cytopenias.

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 37.575mCi/m² of CLR 131 administered in two 30-minute infusions of 18.75mCi/m² of CLR 131 administered on day 1 and day 7 (± 1), with the option for a second dose cycle approximately 75-180 days later. The company expects to report topline data in 2019.

Cellctar 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, cancer-targeting radiotherapeutic Phospholipid Drug ConjugateTM (PDC) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is the company's lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma as well as orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In addition to the ongoing Phase 1 dose-escalation study and the Phase 2 (CLOVER-1) trial, the company recently initiated a Phase 1 open-label, dose-escalating study in pediatric solid tumors and lymphoma to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

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