

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): May 15, 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 August 20, 2019	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRB	NASDAQ Capital Market

ITEM 7.01 REGULATION FD DISCLOSURE

On May 15, 2019, we issued a press release announcing initial results from Cohort 6 in our ongoing Phase 1 clinical study with CLR 131 in Relapsed or Refractory Multiple Myeloma (R/R MM). 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

<u>Number</u>	<u>Title</u>
<u>99.1</u>	<u>Press release dated May 15, 2019, titled “CLR 131 Achieves 50% Overall Response Rate in Cohort 6 of Ongoing Phase 1 Study in Relapsed or Refractory Multiple Myeloma”</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: May 15, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Charles T. Bernhardt

Name: Charles T. Bernhardt

Title: Interim Chief Financial Officer



CLR 131 Achieves 50% Overall Response Rate in Cohort 6 of Ongoing Phase 1 Study in Relapsed or Refractory Multiple Myeloma

Results demonstrated 50% partial response rate, 50% minimal response rate, and 100% disease control rate

Independent Data Monitoring Committee determines dose to be safe and well tolerated and recommends study continue to Cohort 7

FLORHAM PARK, N.J., May 15, 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 initial results from Cohort 6 in the Company's ongoing Phase 1 clinical study with CLR 131 in Relapsed or Refractory Multiple Myeloma (R/R MM). The 37.5mCi/m² fractionated dose was determined to be safe and tolerable by the independent Data Monitoring Committee (DMC). Following the determination, the Company has initiated a Cohort 7 utilizing a 40mCi/m² fractionated dose (20mCi/m² dose on day 1 and day 8).

Data from Cohort 6 showed improved efficacy and a clear dose response compared to prior cohorts, including a 50% partial response rate, a 50% minimal response rate and 100% disease control rate. The International Myeloma Working Group defines a partial response as a 50% to 89.9% reduction in the marker of disease and minimal response as 25% to 49.9% reduction in the marker of disease. One patient achieving a minimal response with a 48% reduction in their marker is still on study and continues to be evaluated.

"We are very pleased to see continued positive safety and tolerability data in addition to enhanced efficacy from our ongoing Phase 1 dose escalation study for CLR 131," said James Caruso, president and CEO of Cellestar. "We are observing a clear dose response with greater and more prolonged median reductions in surrogate efficacy markers throughout the study safety evaluation period as compared to prior cohorts, along with an improved overall drug profile with our fractionated dosing regimen. The Data Monitoring Committee unanimously agreed the study should progress to a Cohort 7 with a higher 40mCi/m² fractionated dose. This cohort has been initiated with data expected in Q4 2019."

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 R/R MM. 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 initiating a Cohort 7 where patients will receive 40mCi/m² fractionated dose of CLR 131.

About CLR 131

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic 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. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted 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.

About Collectar Biosciences, Inc.

Collectar Biosciences is focused on the discovery, development, and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage its PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, Collectar seeks to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and to broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 2 clinical study (CLOVER-1) in R/R MM and select B-cell malignancies, as well as a dose escalation Phase 1 study in patients with R/R MM. The company has initiated a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma.

Collectar'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.

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. 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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