

CELLECTAR BIOSCIENCES, INC.

FORM 8-K (Current report filing)

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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: December 6, 2017
(Date of earliest event reported)

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
(IRS Employer
Identification Number)

3301 Agriculture Drive, Madison, Wisconsin 53716
(Address of principal executive offices)

(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))

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 December 6, 2017, we issued a press release announcing that we will increase the targeted patient enrollment in the relapsed/refractory (R/R) multiple myeloma (MM) cohort of our currently enrolling Phase 2 clinical trial of CLR 131. 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>
99.1	Press release dated December 6, 2017, titled "Cellectar Announces Expansion of Relapsed/Refractory Multiple Myeloma Cohort in Phase 2 Trial of CLR 131"

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 6, 2017

CELLECTAR BIOSCIENCES, INC.

By: /s/ John P. Hamill
Name: John P. Hamill
Title: Interim Chief Financial Officer

Collectar Announces Expansion of Relapsed/Refractory Multiple Myeloma Cohort in Phase 2 Trial of CLR 131

Multiple myeloma cohort exceeded pre-specified criteria for clinically meaningful benefit

Madison, Wis., December 6, 2017 -- Collectar Biosciences (Nasdaq: CLRB), a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announces that the company will increase the targeted patient enrollment in the relapsed/refractory (R/R) multiple myeloma (MM) cohort of its currently enrolling Phase 2 clinical trial of CLR 131. Data from the MM cohort of the study demonstrated that the treatment exceeded pre-specified criteria for clinically meaningful benefit. As a result, the cohort will be expanded up to as many as 40 patients.

“The initial results from the multiple myeloma arm of this Phase 2 study underscore the potential for CLR 131 to benefit these heavily pre-treated and relapsed patients. We continue to see clinical benefit with CLR 131 in both our Phase 1 and Phase 2 clinical studies and look forward to reporting additional data from the both of these clinical studies next year,” stated James Caruso, president and chief executive officer of Collectar Biosciences. “Furthermore, we are pleased to have achieved this key clinical milestone within our projected timelines” added Mr. Caruso.

About the Phase 2 Study of CLR 131

The Phase 2 study is being conducted in approximately 10 leading cancer centers in the United States for patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being studied include (MM, chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL).

The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a single 25.0 mCi/m² dose of CLR 131, with the option for a second 25.0 mCi/m² dose approximately 75-180 days later.

In addition to the CLR 131 infusion(s), MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. Collectar will receive approximately \$2 million in a non-dilutive grant 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 an investigational compound under development for a range of orphan designated cancers. It is currently being evaluated as a single-dose treatment in a Phase I clinical trial in patients with R/R MM as well as in a Phase II clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. Based upon preclinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating solid and hematological tumors and may provide patients with therapeutic benefits, including overall survival, an improvement in progression-free survival, surrogate efficacy marker response rate, and overall quality of life. CLR 131 utilizes the company's patented PDC tumor targeting delivery platform to deliver a cytotoxic radioisotope, iodine-131, directly to tumor cells. The FDA has granted Collectar an orphan drug designation for CLR 131 in the treatment of MM.

About Phospholipid Drug Conjugates (PDCs)

Cellectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). The company deliberately designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate both therapeutic and diagnostic applications. The basis for selective tumor targeting of our PDC compounds lies in the differences between the plasma membranes of cancer cells compared to those of normal cells. Cancer cell membranes are highly enriched in lipid rafts, which are glycolipoprotein microdomains of the plasma membrane of cells that contain high concentrations of cholesterol and sphingolipids, and serve to organize cell surface and intracellular signaling molecules. PDCs have been tested in more than 80 different xenograft models of cancer.

About Cellectar Biosciences, Inc.

Cellectar Biosciences (Nasdaq:CLRB) is developing phospholipid drug conjugates (PDCs) designed to provide cancer targeted delivery of diverse oncologic payloads to a broad range of cancers and cancer stem cells. Cellectar's PDC platform is based on the company's proprietary phospholipid ether analogs. These novel small-molecules have demonstrated highly selective uptake and retention in a broad range of cancers, even sites of metastases. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 has been designated as an orphan drug by the U.S. FDA and is currently being evaluated in a Phase 1 clinical study in patients with relapsed or refractory multiple myeloma and a Phase 2 clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing proprietary PDCs for targeted delivery of chemotherapeutics and has several preclinical stage product candidates, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For more information please visit www.cellectar.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 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, 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, 2016. 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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