

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: May 18, 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, WI 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))
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ITEM 7.01 REGULATION FD DISCLOSURE

On May 18 , 2017, we issued a press release announcing preclinical data from three abstracts demonstrating the utility of the Company’s lead compound, CLR 131, for use in a variety of tumor types in single-dose and multi-dose regimens. The abstracts were published as part of the 2017 ASCO Annual Meeting Proceedings. 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
99.1	Press release dated May 18 , 2017, entitled “Three Abstracts on Dosing Regimens of Collectar’s CLR 131 in a Variety of Tumor Types Published in the <i>2017 ASCO Annual Meeting Proceedings</i> ”

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 18, 2017

CELLECTAR BIOSCIENCES, INC.

By: */s/ Chad J. Kolean*

Name: Chad J. Kolean

Title: Vice President and Chief Financial Officer

Three Abstracts on Dosing Regimens of Collectar's CLR 131 in a Variety of Tumor Types Published in the 2017 ASCO Annual Meeting Proceedings

Madison, Wisc. (May 18, 2017) -- Collectar Biosciences, Inc. (Nasdaq: CLRB), (the "company"), an oncology-focused, clinical stage biotechnology company, today announces preclinical data from three abstracts demonstrating the utility of the company's lead compound, CLR 131, for use in a variety of tumor types in single-dose and multi-dose regimens. The abstracts were published as part of the *2017 ASCO Annual Meeting Proceedings*.

"These peer-reviewed studies, while early stage, further demonstrate the variety of potential applications and dosing regimens for CLR 131. In these preclinical models, we have observed measurable reduction compared to a control in tumor growth of three different cancer types while also showing a clear survival benefit," said Jim Caruso, president and CEO of Collectar Biosciences. "While CLR 131 is currently in Phase 1 and Phase 2 trials for blood cancers, the publication of these abstracts indicate promise in solid tumors, and provide further data on the potential benefit of a multi-dose regimen."

In the first study, 20 mice were injected with glioma (brain) tumor cells (U87-MG). Investigators then injected two doses of CLR 131 (95.7 μ Ci and 109.0 μ Ci on day 0 and day 7, respectively) or a control group of I-127-CLR 1404 (N=8 per group). The expected 25-fold increase in tumor burden observed in the control arm over the four-week study was reduced by 50 percent in the CLR 131 arm with additional survival benefit. In fact, the two doses of CLR 131 provided a 50 percent increase in survival over a single dose of CLR 131 in the same model.

The second study involved female mice receiving two doses of CLR 131 (approximately 130 μ Ci and approximately 145 μ Ci at days 0 and 20, respectively) as well as a control group of I-127-CLR 1404 (N=8 per group), following injection of female mice with a MES SA/Dx5 cell line (human uterine sarcoma). This model was selected because of its high level of expression of resistance mechanisms these tumor cells exhibit, specifically P-gp efflux pumps that eject many chemotherapeutics from the cell. The active treatment group (CLR 131) experienced a 66 percent reduction of the expected 21-fold increase in tumor burden observed in the control group. This resulted in nearly doubling the survival time for the mice receiving two doses of CLR 131.

The final study entailed the injection of mice with Caki-2 cell line (human clear cell carcinoma, common in renal cancer). Once tumor size reached a pre-determined volume, these mice received either a single dose of CLR 131 (approximately 110 μ Ci), or a control of I-127-CLR 1404 (N=8 per group). The control group showed exponential growth at 20 days post-injection, while the treatment group experienced a reduction in the initial tumor volume through day 65 post-injection and had the same initial tumor volume at day 75 post-injection. By day 65, the control group increased 10.75-fold compared to the treatment group in average tumor volume.

About CLR 131

CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated as a single-dose treatment in a Phase 1 clinical trial in patients with relapsed or refractory (R/R) multiple myeloma (MM) as well as in a Phase 2 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 1 study data, treatment with CLR 131 provides a novel approach to treating hematological diseases 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 Cellectar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

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 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. Cellectar's PDC pipeline includes product candidates for cancer therapy and cancer diagnostic imaging. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 is currently being evaluated under an orphan drug designated Phase 1 clinical study in patients with relapsed or refractory multiple myeloma. In addition, the company has initiated a Phase 2 clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1602-PTX), a preclinical stage product candidate, 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.

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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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