

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: February 22, 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 February 22, 2017, we issued a press release announcing the successful completion of Cohort 3 and initiation of Cohort 4 in the Company's Phase I clinical study of CLR 131 in patients with relapsed and refractory multiple myeloma. 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 February 22, 2017, entitled "Upon Successful Completion of Cohort 3, Cellectar Biosciences Initiates Fourth Cohort of Its Phase I Clinical Trial of CLR 131 in Multiple Myeloma – 25mCi/m2 Dose Determined to Be Safe and Well-Tolerated"

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: February 22, 2017

CELLECTAR BIOSCIENCES, INC.

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Vice President and Chief Financial Officer

Upon Successful Completion of Cohort 3, Collectar Biosciences Initiates Fourth Cohort of Its Phase I Clinical Trial of CLR 131 in Multiple Myeloma*25mCi/m² Dose Determined to Be Safe and Well-Tolerated*

Madison, Wis. (February 22, 2017) -- Collectar Biosciences, Inc. (Nasdaq: CLRB), an oncology-focused clinical stage biotechnology company, today announces the successful completion of Cohort 3 and initiation of Cohort 4 in the company's Phase I clinical study of CLR 131 in patients with relapsed and refractory multiple myeloma.

The fourth cohort of the Phase 1 study will consist of at least three patients with relapsed or refractory multiple myeloma that have been treated previously with at least one proteasome inhibitor and one immunomodulatory agent. Per protocol, Cohort 4 patients will receive 31.25 mCi/m² of CLR 131 as a single dose infusion, a 25 percent increase in the 25 mCi/m² dose from the third cohort and a 150 percent increase from Cohort 1, all of which were demonstrated to be safe and well tolerated. It is important to note that a key objective of this Phase I clinical trial includes the establishment of the maximum tolerated single dose of CLR 131 as defined by the occurrence of dose limiting toxicities.

Initiation of the fourth cohort occurs well ahead of the company's guidance, which called for initiation to occur at the end of the second quarter of 2017. Further, the company continues to follow all 12 evaluable patients in each of the three previously completed cohorts, which include eight patients from Cohorts 1 and 2 who continue to extend median overall survival. Collectar expects to provide a detailed data update on these patients by the end of the second quarter of 2017.

"Our enthusiasm for CLR 131's potential in multiple myeloma patients continues to grow given the positive safety, efficacy markers, progression-free survival and median overall survival results that we have observed to date in the Phase I trial, particularly given such a heavily pretreated patient population," said Jim Caruso, president and CEO of Collectar Biosciences. "We will explore the potential enhanced clinical benefits of a two-dose regimen in our imminent Phase II study, and look forward to updating investors on results of the fourth cohort when available."

The primary study objective of this multi-center, open label Phase I dose escalation study is to characterize the safety and tolerability of CLR 131 administered as a single dose, 30-minute infusion in patients with relapsed or refractory multiple myeloma. Secondary study objectives include establishment of a recommended single dose for Phase II, both with and without dexamethasone, as well as an assessment of therapeutic activity.

In addition, the company recently brought forward guidance for the initiation of its NCI-supported Phase II trial in multiple myeloma and other selected hematologic cancers to the first quarter of 2017. The company expects that all patients will receive a single dose of CLR 131 at 25 mCi/m² infused over approximately 30 minutes, with the option of a second 25 mCi/m² dose 75-180 days later, based upon physician assessment. The Phase II study will be conducted in up to 15 centers across the United States and Collectar anticipates initial efficacy data as early as the second half of 2017.

About CLR 131

CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated in a Phase I clinical trial in patients with relapsed or refractory multiple myeloma. The company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. Based upon pre-clinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating hematological diseases and may provide patients with therapeutic benefits, including overall response rate (ORR), an improvement in progression-free survival (PFS) 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 multiple myeloma.

About Phospholipid Drug Conjugates (PDCs)

Collectar'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 Collectar Biosciences, Inc.

Collectar 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. Collectar'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. Collectar'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 I clinical study in patients with relapsed or refractory multiple myeloma. In addition, the company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1603-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.collectar.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/A for the year ended December 31, 2015. 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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