
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: September 24, 2018
(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 September 24, 2018, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) has initiated direct talks with us concerning a possible exemption for CLR 131 from the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC), the sole supplier of Collectar’s drug 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

Number	Title
<u>99.1</u>	<u>Press release dated September 24, 2018, titled “Collectar Biosciences Provides an Update on the FDA Import Alert”</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: September 24, 2018

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

Collectar Biosciences Provides an Update on the FDA Import Alert

MADISON, Wis., September 24, 2018 – Collectar Biosciences, Inc. (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, announces today that the U.S. Food and Drug Administration (FDA) has initiated direct talks with the company concerning a possible exemption for CLR 131 from the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC), the sole supplier of Collectar's drug CLR 131.

As announced on August 10, 2018, Collectar was informed by CPDC of the Import Alert on August 7, 2018, and further learned that the basis for the Import Alert was not related to CLR 131 or to CPDC's production facility associated with CLR 131. Since notification of the Import Alert, Collectar has been actively assisting CPDC to secure the timely removal of the Import Alert. Recently, the FDA initiated direct talks with Collectar on a potential pathway to remove CLR 131 from the Import Alert and allow CPDC to resume supply of CLR 131.

"We are encouraged that the FDA initiated a direct dialogue with us regarding a potential resolution for the Import Alert that is affecting CLR 131," said James Caruso, president and CEO of Collectar Biosciences. "This issue remains a top priority for Collectar and although we are not currently able to assess whether the FDA will exempt CLR 131 from the Import Alert, we are working closely with the agency and plan to respond quickly to any information requests."

About CLR 131

CLR 131 is Collectar's investigational radioiodinated PDC therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131 is in a Phase 2 clinical study in R/R MM and a range of B-cell malignancies and a Phase 1b clinical study in patients with R/R MM exploring fractionated dosing. The objective of the multicenter, open-label, Phase 1b dose-escalation study is the characterization of safety and tolerability of CLR 131 in patients with R/R MM. Patients in Cohorts 1-4 received single doses of CLR 131 ranging from 12.5 mCi/m² to 31.25 mCi/m² as well as a fractionated dose of 15.625 mCi/m² given twice over seven days in Cohort 5. All study doses and regimens have been deemed safe and well tolerated by an independent Data Monitoring Committee. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer.

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 our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 1 clinical study in patients with R/R MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

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, 2017 and our Form 10-Q for the quarterly period ended June 30, 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.

CONTACT:

LHA Investor Relations
Miriam Weber Miller
212-838-3777
mmiller@lhai.com

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