
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 4, 2018
(Date of earliest event reported)

COLLECTAR 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)

100 Campus Drive, Florham Park, New Jersey 07932
(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 4, 2018, we issued a press release announcing the initiation of Cohort 6 of our ongoing Phase 1b trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (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

Number	Title
<u>99.1</u>	<u>Press release dated December 4, 2018, titled “Cellestar Initiates Cohort 6 of Phase 1b Trial Evaluating CLR 131 in Relapsed/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: December 4, 2018

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

Collectar Initiates Cohort 6 of Phase 1b Trial Evaluating CLR 131 in Relapsed/Refractory Multiple Myeloma***Patient enrolled at highest fractionated two-dose regimen to date***

FLORHAM PARK, N.J. (December 4, 2018) – Collectar Biosciences (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, announces the initiation of Cohort 6 of its ongoing Phase 1b trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (MM). Cohort 6 will evaluate up to four patients with each receiving two doses of 18.75 mCi/m² of CLR 131 administered one week apart. This fractionated dosing regimen will result in each patient being treated with a total of approximately 75.0 mCi of CLR 131, representing an increase in average total exposure of greater than 15% over Cohort 5.

Cohort 5 also used a fractionated dosing regimen and results showed an ability to administer higher average drug exposure compared with previous cohorts that used bolus dosing. The results seen in Cohort 5 suggest the potential of fractionated dosing to reduce adverse events while improving efficacy. The independent Data Monitoring Committee (DMC) determined the Cohort 5 dose to be safe and well tolerated, and the DMC recommended advancement to the higher dose being used in Cohort 6.

“Cohort 6 builds upon the fractionated dosing we successfully employed with Cohort 5, and we look forward to the results from utilizing a higher drug concentration in this two-dose fractionated approach,” said James Caruso, president and chief executive officer of Collectar Biosciences. “Importantly,” Caruso continued, “while cohort 5 showed fewer adverse events than cohort 4, total radiation exposure was greater.”

Cohort 5 Results

Results from Cohort 5 indicated enhanced tolerability and safety compared with Cohort 4 despite an 18% increase in total average dose, from 55.29 mCi in Cohort 4 to 65.15 mCi in Cohort 5. Patients in Cohort 5 required less supportive care such as transfusions of platelets or packed red blood cells than seen in previous cohorts.

In addition to the improved safety profile demonstrated in Cohort 5, the company also monitored signals of efficacy. Despite Cohort 5 patients averaging five lines of prior systemic therapies, all patients experienced clinical benefit with two patients achieving minimal responses and two achieving stable disease. Furthermore, looking at surrogate markers, patients in Cohort 5 monitored by M-protein showed a nearly 50% further reduction in M-protein than seen in Cohort 4.

Based on these results and the DMC recommendation, Collectar plans to modify the single-dose regimen of its ongoing Phase 2 trial of R/R hematologic malignancies to fractionated dosing.

About CLR 131

CLR 131 is Collectar's investigational radioiodinated phospholipid ether-drug conjugate (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 relapsed/refractory multiple myeloma (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 plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma as well as a second Phase 1 study in combination with external beam radiation for head and neck cancer.

About Phospholipid Drug Conjugates™

Collectar's product candidates are built upon a patented delivery and retention platform that utilizes optimized PDCs to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Collectar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

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 plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma as well as a second Phase 1 study in combination with external beam radiation for head and neck cancer.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and partnered assets including PDCs from multiple R&D collaborations.

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 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 September 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.

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