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 (Date of earliest event reported): **September 22, 2021**

CELLECTAR BIOSCIENCES, INC.

(*Exact name of registrant as specified in its charter*)

Delaware	**1-36598**	**04-3321804**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

100 Campus Drive, Florham Park, New Jersey 07932
(*Address of principal executive offices, and zip code*)

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.00001	CLRB	NASDAQ Capital Market

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 22, 2021, we issued a press release announcing the completion of the part A portion of a safety and tolerability study of iopofosine I-131 (iopofosine) in combination with external beam radiation (EBRT) in relapsed or refractory head and neck cancer. 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 September 22, 2021, titled "Preliminary Data with Iopofosine I-131 in Combination with External Beam Radiation Suggests Safety and Tolerability in Relapsed or Refractory Head and Neck Cancer"
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

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 22, 2021

CELLECTAR BIOSCIENCES, INC.

By: */s/ Dov Elefant*
Name: Dov Elefant
Title: Chief Financial Officer

Exhibit 99.1

Preliminary Data with Iopofosine I-131 in Combination with External Beam Radiation Suggests Safety and Tolerability in Relapsed or Refractory Head and Neck Cancer

Initiation of Expansion Cohort of Up to 24 Patients

FLORHAM PARK, N.J., September 22, 2021 -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, today announced the completion of the part A portion of a safety and tolerability study of iopofosine I-131 (iopofosine) in combination with external beam radiation (EBRT) in relapsed or refractory head and neck cancer. This Investigator initiated study is being conducted by the University of Wisconsin as part of a prestigious Specialized Program of Research Excellence (SPORE) grant awarded by the National Cancer Institute.

The University of Wisconsin clinical trial under direction of principal investigator, Dr. Justine Yang Bruce is evaluating the potential for iopofosine in combination with EBRT to reduce the total dose (Grays) and number of fractions of external beam radiation while maintaining favorable tumor response rates.

The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with head and neck cancer typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a 6 week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study will further assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients.

"These preliminary study results support the potential promise of iopofosine. We are pleased that the early phase of the University of Wisconsin study has demonstrated good tumor uptake of iopofosine at the planned doses as well as safety of this unique treatment approach in Head & Neck cancer patients," said John Friend, CMO of Cellectar. "We remain cautiously optimistic that iopofosine in combination with external beam radiation may offer improved outcomes for patients in this highly challenging to treat disease."

Dr. Justine Yang Bruce stated "Iopofosine offers a novel investigational approach for patients with difficult to treat tumors such as head and neck cancer. The ability to potentially reduce the total external beam radiation doses is meaningful and we look forward to continue exploring iopofosine's potential as a combination treatment in this indication."

In addition to head and neck cancer, Cellectar is currently investigating iopofosine in a global, pivotal expansion cohort in relapsed or refractory Waldenstrom's macroglobenemia (WM) patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs independently and through research and development collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop PDCs that specifically target cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit www.cellectar.com and www.wmclinicaltrial.com or join the conversation by liking and following us on the company's social media channels: Twitter, LinkedIn, and Facebook.

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 including our expectations of the impact of the COVID-19 pandemic. 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 iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for iopofosine, 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, 2020. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

Contacts

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