

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): **August 16, 2021**

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
(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 August 16, 2021, we issued a press release announcing that we have entered into a commercial manufacturing and supply agreement with Evergreen Theragnostics, a global radiopharmaceutical contract development and manufacturing organization (CDMO) based in Springfield, NJ. 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 August 16, 2021, titled "Cellectar Announces Manufacturing and Supply Agreement with Evergreen Theragnostics for CLR-131, now known as iopofosine I-131"
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: August 16, 2021

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov *Elefant*

Name: Dov Elefant

Title: Chief Financial Officer



Collectar Announces Manufacturing and Supply Agreement with Evergreen Theragnostics for CLR-131, now known as iopofosine I-131

Evergreen to provide clinical and commercial supply of iopofosine I-131 (also known as CLR 131)

Agreement adds second manufacturer and expands Collectar's current supply capabilities

FLORHAM PARK, N.J., August 16, 2021 -- Collectar 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 that it has entered into a commercial manufacturing and supply agreement with Evergreen Theragnostics, a global radiopharmaceutical contract development and manufacturing organization (CDMO) based in Springfield, NJ. The company also announced that the United States Adopted Names Council (USAN) has approved the use of "iopofosine I-131" as the generic name for CLR-131.

The agreement with Evergreen provides long term commercial supply of iopofosine I-131 and supply of clinical study material for Collectar's pivotal study in Waldenström's macroglobulinemia (WM) as well as ongoing Phase 1 and Phase 2 clinical studies. Evergreen will conduct process development and validation of additional large scale commercial quantities of iopofosine I-131 at its newly constructed, state-of-the-art manufacturing facility designed specifically for radiopharmaceutical manufacturing, including therapeutic and diagnostic radiopharmaceuticals.

"Establishing a collaboration with a strong partner capable of supplying clinical and commercial scale quantities of iopofosine I-131 is another important advancement in our iopofosine I-131 product development and commercialization plan," said James Caruso, president and CEO of Collectar. "Evergreen has tremendous expertise as a leading radiopharmaceutical contract manufacturer, and their location in New Jersey provides strategic logistical advantages including favorable distribution for both the U.S. and ex-U.S. markets. Importantly, this collaboration expands upon our current supply capabilities with our existing CDMO, allows future development and supply of additional radiotherapeutic programs in development and continues to pave the way for Collectar to meet the potential market demand for iopofosine I-131 upon approval."

James Cook, CEO of Evergreen Theragnostics stated that, "We welcome this new collaboration with Collectar Biosciences. Iopofosine I-131 represents a unique and novel class of radiotherapeutics and Evergreen is excited to participate in its continued development and long-term supply to patients. We look forward to working with Collectar on this and future programs."

Iopofosine I-131 is currently being investigated in a global, pivotal expansion cohort in WM patients who have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitor failed or suboptimal response. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine I-131 for marketing approval. The company is also evaluating iopofosine I-131 in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study in hematologic malignancies.

About Evergreen Theragnostics, Inc.

Evergreen Theragnostics, established in 2019, is a leading US-based radiopharmaceutical Contract Development and Manufacturing Organization (CDMO). With a state-of-the-art global GMP facility, Evergreen provides highly reliable manufacturing services for therapeutic and centrally distributed diagnostic radiopharmaceuticals, from early development through commercialization. The company was founded by a team that brings a strong track record in theragnostic radiopharmaceutical commercialization, manufacturing process development, and regulatory affairs management. For more information, please visit www.evergreentgn.com.

About Collectar Biosciences, Inc.

Collectar 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 I-131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The Company is currently enrolling in a global, pivotal Phase 2 Part B (CLOVER-WaM) expansion study in WM patients who have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitor failed or suboptimal response patients. The WM study will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine I-131 for marketing approval.

For more information, please visit www.collectar.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 I-131, 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 I-131, 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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