UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): October 6, 2025

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 Number)

100 Campus Drive, Florham Park, NJ, 07932
(Address of Principal Executive Offices) (Zip Code)

(608) 441-8120
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 per share	CLRB	NASDAQ

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:

¨ 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

¨ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended 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 October 6, 2025, Cellectar Biosciences, Inc. (the "Company") issued a press release announcing that after a scientific advice procedure, the Scientific Advice Working Party ("SAWP") of the European Medicines Agency ("EMA") advised that filing for a Conditional Marketing Authorization ("CMA") for iopofosine I 131 as a treatment for post-Bruton Tyrosine Kinase inhibitor ("BTKi") refractory patients with Waldenstrom macroglobulinemia ("WM") could be acceptable for a CMA. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Item 7.01 Current Report on Form 8-K, including Exhibit 99.1 hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On October 6, 2025, the Company announced that after a scientific advice procedure, SAWP advised that filing for a CMA for iopofosine I 131 as a treatment for post- BTKi refractory patients with WM could be acceptable for a CMA. There is no guarantee of CMA approval; however, if iopofosine I 131 is granted a CMA, it could potentially begin to be commercially available in the 30 countries represented by the EMA as early as 2027.

The Company's decision to file for CMA in Europe follows SAWP's advice on the patient population for which iopofosine I 131 is acceptable for a CMA, particularly a discussion on a post BTKi patient population, consistent with the majority of the patients (>70%) enrolled in the CLOVER WaM Phase 2 study. The Company's briefing document to the SAWP included iopofosine I 131's safety database, CLOVER WaM clinical study results, subset analyses, and manufacturing information. It is not within the remit of the SAWP to determine whether the data shows the sufficiency of safety and efficacy for a CMA; however, the SAWP advised that iopofosine I 131 met the eligibility requirements for a CMA submission for the proposed patient population. As in the U.S., there remains a significant unmet medical need for the treatment of WM in Europe, where the condition affects an estimated 35,000 to 45,000 patients.

Although during the scientific advice procedure SAWP advised that filing a CMA for iopofosine I 131 as a treatment for post-BTKi refractory patients with WM could be acceptable, this feedback is not a guarantee of final CMA approval, and we do not know how the EMA will interpret the data and results from our clinical trials and other elements of our development program. The EMA may raise issues of, for example, safety, efficacy, study conduct, bias, deviation from the protocol, statistical power and analyses, patient demographics, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. There is no guarantee that the EMA will not require that we conduct one or more additional clinical trials or nonclinical studies to support potential CMA approval, or that iopofosine I 131 will receive any regulatory approvals in the EU. Scientific advice is legally non-binding with regard to any future CMA application and it is beyond the remit of the SAWP to determine whether the data shows sufficient safety and efficacy for a CMA. Companies which have been provided with positive scientific advice by SAWP have ultimately failed to obtain approval of a CMA or marketing authorization for their drugs.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release, dated October 6, 2025
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.

CELLECTAR BIOSCIENCES, INC.

Date: October 6, 2025

By: */s/ Chad J. Kolean*
Chad J. Kolean
Chief Financial Officer

Exhibit 99.1

Cellectar Biosciences Announces European Medicines Agency (EMA) Confirms Eligibility to File for Conditional Marketing Authorization (CMA) for Iopofosine I 131 as a Treatment for Refractory (post-BTKi) Waldenstrom Macroglobulinemia (WM)

Following Scientific Advice and Guidance from Scientific Advice Working Party (SAWP) of EMA, Submission of CMA Application for Iopofosine I 131 as a Treatment for Refractory (post-BTKi) WM Expected in Early 2026

Potential 2027 European Approval and Commercial Launch of Iopofosine I 131 as a Treatment for Refractory (post-BTKi) WM

FLORHAM PARK, N.J., October 6, 2025 (GLOBE NEWSWIRE) -- 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 that after a scientific advice procedure, the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) advised that filing for a Conditional Marketing Authorization (CMA) for iopofosine I 131 as a treatment for post-Bruton Tyrosine Kinase inhibitor (BTKi) refractory patients with Waldenstrom macroglobulinemia (WM) could be acceptable for a CMA. If approved, iopofosine I 131 could be commercially available in the 30 countries represented by the EMA in 2027.

Iopofosine I 131 is Cellectar's potential first-in-class, novel cancer targeting agent utilizing the company's proprietary phospholipid ether as a radioconjugate monotherapy, for the treatment of WM for post-Bruton Tyrosine Kinase inhibitor (BTKi) refractory patients. Iopofosine I 131 has been granted PRIME designation from the EMA for the treatment of patients with WM who received at least two prior lines of therapy. WM is a B-cell malignancy characterized by bone marrow infiltration with clonal lymphoplasmacytic cells that produce a monoclonal immunoglobulin M (IgM) that remains incurable with available treatments.

The Company's decision to file for CMA in Europe follows SAWP's advice on the patient population for which iopofosine I 131 is acceptable for a CMA, particularly a discussion on a post-BTKi patient population, consistent with the majority of the patients (>70%) enrolled in the CLOVER WaM Phase 2 study. Cellectar's briefing document to the SAWP included iopofosine I 131's safety database, CLOVER WaM clinical study results, subset analyses, and manufacturing information. It is not within the remit of the SAWP to determine whether the data shows the sufficiency of safety and efficacy for a CMA; however, the SAWP advised that iopofosine I 131 met the eligibility requirements for a CMA submission for the proposed patient population. As in the U.S., there remains a significant unmet medical need for the treatment of WM in Europe, where the condition affects an estimated 35,000 to 45,000 patients.

"We are thrilled to take this important step toward bringing iopofosine I 131 to patients in Europe living with WM. With PRIME designation already in hand and feedback from the SAWP, we are rapidly proceeding toward a potential European approval and commercial availability in 2027," stated James Caruso, president and CEO of Cellectar. "We believe this regulatory success is substantial as it further supports Cellectar's plans to pursue worldwide approval, including a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) under an accelerated approval pathway, and today's milestone brings us closer to making that a reality. While submission and conditional approval of an NDA is contingent upon the company obtaining additional funding to support the U.S. confirmatory study initiation, iopofosine I 131 may be approved and commercialized in the EU prior to the initiation of a confirmatory study."

The CLOVER WaM study (NCT02952508) results demonstrated an overall response rate (ORR) of 83.6% and a major response rate (MRR) of 58.2% (95% CI, 0.42 to 0.67). These data were presented as a podium presentation during the 66th Annual American Society of Hematology Conference in December 2024 by Sikander Ailawadhi, M.D., Professor of Medicine, Mayo Clinic. The full presentation can be accessed here. https://d1io3yog0oux5.cloudfront.net/_42e6ad79bb6b588ab8d31bd76b800b66/cellectar/db/422/3348/pdf/P03834_ASH2024Presentation_cloverwam_12.6.24+%28002%29+copy+copy-compressed+%281%29.pdf

“Our planned submission for CMA in Europe represents a significant milestone—not only for patients, but also for our global strategy. Iopofosine I 131 offers a highly attractive profile for potential partners, with compelling patient outcomes, convenient fixed dosing, “off-the-shelf” supply that supports scalable access across geographies, and multiple long-term isotope supply agreements to provide nearly uninterrupted supply. Combined with orphan drug pricing and PRIME designation, we believe this program presents a substantial market opportunity and a clear path to value creation through regional and global collaborations,” said Jarrod Longcor, chief operating officer of Cellectar.

The U.S. NDA will be submitted once the confirmatory trial is underway and will be supported by data from the Phase 2b CLOVER WaM clinical trial that demonstrated a statistically significant major response rate compared to a null hypothesis of 20% and meaningful duration of response. The data set now includes the FDA-requested 12-month follow-up results on all patients from the trial and new subset analysis of data from patients immediately following BTKi treatment failures regardless of line of therapy. The Company plans to share these new data at an upcoming medical or scientific conference.

About Conditional Market Authorization

Conditional Marketing Authorization (CMA) is a regulatory pathway offered by EU legislation that enables earlier access to medicines that address unmet medical needs, particularly in serious or life-threatening conditions. CMA allows for approval based on less comprehensive clinical data than normally required, provided the benefit of the immediate availability on the market of the relevant medicinal product outweighs the risk that additional data are still required and the applicant is likely to be able to provide comprehensive data.

About Scientific Advice Working Party

The Scientific Advice Working Party (SAWP) is a standing working party within the EMA with the sole remit of providing scientific advice and protocol assistance. It was established by the Committee for Medicinal Products for Human Use (CHMP).

The SAWP is a multidisciplinary group, which comprises a chairperson, 36 members including three members of the Committee for Orphan Medicinal Products (COMP), three members of the Paediatric Committee (PDCO), three members of the Committee for Advanced Therapies (CAT) and one member of the Pharmacovigilance Risk Assessment Committee (PRAC).

About PRIME Designation

The European Medicines Agency’s (EMA) PRIME (PRIority MEdicines) designation is a regulatory initiative designed to enhance support for the development of medicines that target unmet medical needs. PRIME provides early and proactive engagement with developers to optimize clinical development plans and accelerate regulatory review, helping promising therapies reach patients sooner. Products granted PRIME status benefit from enhanced scientific advice, dedicated EMA support, and eligibility for accelerated assessment at the time of marketing authorization application.

About Waldenstrom's Macroglobulinemia

Waldenstrom's Macroglobulinemia (WM) is a B-cell malignancy characterized by bone marrow infiltration with clonal lymphoplasmacytic cells that produce a monoclonal immunoglobulin M (IgM) that remains incurable with available treatments. The prevalence in the US is approximately 26,000 with 1,500–1,900 patients being diagnosed annually. Approximately 11,500 patients require treatment in the relapsed or refractory setting and there are an estimated 4,700 patients requiring third line or greater therapy. There are also approximately 1,000 patients that have exhausted all current treatment options by third line because they are ineligible or intolerant to those existing therapies. Therefore, the total addressable market for third line or greater therapy is approximately 5,700 patients. There are no U.S. Food and Drug Administration (FDA) approved treatment options for patients progressing on BTKi therapy. BTKi therapies do not demonstrate complete response rates and require continuous treatment.

Non-FDA approved treatments are used in more than 60% of patients. Over 50% of patients are treated with the same or similar treatment from prior lines of therapy. There is an established unmet need for new FDA-approved treatment like iopofosine I 131 that provide a novel mechanism of action, increased deep durable responses, and time limited treatment, especially in heavily pretreated WM patients.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer, 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 the next-generation of cancer cell-targeting treatments, delivering improved efficacy and better safety as a result of fewer off-target effects.

The company's product pipeline includes its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope); CLR 121225, an actinium-225 based program being targeted to several solid tumors with significant unmet need, such as pancreatic cancer; and CLR 121125, an iodine-125 Auger-emitting program targeted in other solid tumors, such as triple negative breast, lung and colorectal, as well as proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

In addition, iopofosine I 131 has been studied in Phase 2b trials for relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma, and the CLOVER-2 Phase 1b study, targeting pediatric patients with high-grade gliomas, for which Cellectar is eligible to receive a Pediatric Review Voucher from the FDA upon approval. The FDA has also granted iopofosine I 131 six Orphan Drug, four Rare Pediatric Drug and two Fast Track Designations for various cancer indications.

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

Forward Looking Statements 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 FDA and EMA regulatory pathways, ability to execute strategic alternatives, identify suitable collaborators, partners, licensees or purchasers for our product candidates and, if we are able to do so, to enter into binding agreements with regard to any of the foregoing, or to raise additional capital to support our operations, or our ability to fund our operations if we are unsuccessful with any of the foregoing. 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, 2024, and our Form 10-Q for the quarterly period ending June 30, 2025. 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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