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): December 10, 2024

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)**	**(IRS Employer Identification No.)**

100 Campus Drive, Florham Park, NJ, 07932
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (608) 441-8120

N/A
(Former Name or Former Address, if Changed Since Last Report)

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 per share	**CLRB**	The **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 2.05 Costs Associated with Exit or Disposal Activities

On December 10, 2024, the Board of Directors of Cellectar Biosciences, Inc. (the "Company") approved and management began implementing a workforce reduction plan to reduce operating costs and better align its workforce with the needs of its business following recent communications with the U.S. Food and Drug Administration (the "FDA") regarding its confirmatory study to support accelerated approval and the regulatory submission for iopofosine I 131, as described in more detail in Item 8.01 below. The implementation of the workforce reduction plan should be complete by the end of the fourth quarter 2024.

Under the workforce reduction plan, the Company is reducing its overall workforce by approximately 60%. Impacted employees are eligible to receive severance benefits, including: (a) salary continuation for period to be determined on an individual basis, but in no event for less than six weeks, (b) COBRA premium subsidies for the full months that encompass the severance period, and (c) a severance incentive. These severance benefits are contingent upon an impacted employee's execution (and non-revocation) of a separation agreement, which includes a general release of claims against the Company. In addition, any unvested and outstanding stock option grant held by impacted employees that would have vested within 90 days of the termination date will be immediately fully vested and all vested stock options held by such employees shall remain exercisable for 180 days from date of such employee's termination.

The Company expects that the workforce reduction will decrease its annual operating costs by approximately $7.5 million. Additionally, the Company estimates that it will incur aggregate severance costs of approximately $1.7 million, which will be recorded primarily in the fourth quarter of 2024 and first quarter of 2025. The cost that the Company expects to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction.

This Item 2.05 contains forward-looking statements, including, but not limited to, statements related to the expected costs associated with termination benefits and the financial impact of the reduction in force. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to cost reduction efforts. In addition, the Company's workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on the Company's development activities. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2023, and the Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission (the "SEC"), and the Company's subsequent current reports filed with the SEC. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 2.05 as a result of new information, future events or changes in its expectations.

Item 7.01 Regulation FD Disclosure.

On December 10, 2024, the Company issued a press release announcing a strategic update on clinical developments, pipeline programs and corporate restructuring. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Due to recent communications with the FDA regarding a confirmatory study to support accelerated approval and the regulatory submission for iopofosine I 131, the Company has decided to pursue strategic options for the further development and commercialization of iopofosine I 131. Based upon a recent Type-C meeting with the FDA, the Company now believes that a submission seeking accelerated approval would need to be based on the major response rate (MRR) data from CLOVER-WaM and enrollment in a randomized, controlled confirmatory study that is designed to generate data on progression-free survival (PFS).

Cellectar will now focus on those assets it believes have the highest therapeutic potential and opportunity for value creation. The Company believes that precision isotopes like alpha- and Auger-emitters have emerged as the leading therapeutics of interest. Consequently, the Company will now focus its resources on targeting solid tumors by advancing CLR 121225, its actinium-225 based program, and CLR 121125, its iodine-125 Auger-emitting program into the clinic.

Cellectar expects to file Investigational New Drug ("IND") applications in the first half of 2025 for both CLR 121225 and CLR 121125 which will allow the initiation of Phase 1 clinical studies in solid tumor cancers. Both programs have demonstrated robust in vivo activity, tolerability, excellent targeting and uptake in preclinical solid tumor models. The Company believes this approach will provide an expedited timeframe to achieve safety and proof-of-concept data in patients.

The Company's strategic reprioritization will impact all departments and result in an immediate reduction in headcount of approximately 60% and should be complete by the end of the fourth quarter 2024. The Company anticipates that the implementation of the restructuring will extend its cash runway into the third quarter of 2025.

This Item 8.01 contains forward-looking statements, including, but not limited to, statements related to strategic options that the Company may pursue in connection with the further development and commercialization of iopofosine I 131, expectations related to the filing of IND applications for CLR-121225 and CLR-121125, timing of initiation of Phase 1 clinical studies, and the financial impact, including cash runway, of the reduction in force. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. A further description of the risks and uncertainties relating to the business of the Company is contained in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2023, and the Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission (the "SEC"), and the Company's subsequent current reports filed with the SEC. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 8.01 as a result of new information, future events or changes in its expectations.

Item 9.01 Financial Statements and Exhibits.

Number	Title
99.1	Press Release, dated December 10, 2024
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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: December 11, 2024

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

Exhibit 99.1

December 10, 2024

Cellectar Biosciences Provides Strategic Update on Clinical Development, Pipeline Programs and Corporate Restructuring

Evaluating strategic options for iopofosine I 131 a late-stage clinical program with compelling Phase 2 data and a substantial market opportunity

Focusing on advancing radiotherapeutic assets including alpha- and Auger-emitting radioconjugates into Phase 1 solid tumor studies

FLORHAM PARK, N.J., Dec. 10, 2024 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announces a strategic update on its clinical development programs for its proprietary phospholipid ether drug conjugate platform that delivers a broad array of therapeutic modalities to target cancers.

Due to recent communications with the U.S. Food and Drug Administration (FDA, or the Agency) regarding a confirmatory study to support accelerated approval and the regulatory submission for iopofosine I 131, the Company has decided to pursue strategic options for the further development and commercialization of this product candidate. The CLOVER-WaM study was conducted in accordance with earlier FDA communications from an end of Phase 2 meeting and from a meeting in early 2024, during which the Company was informed that positive results for major response rate (MRR) as the primary endpoint could be acceptable to support accelerated approval of iopofosine I 131 as a treatment for Waldenstrom's macroglobulinemia (WM). Based upon a recent Type-C meeting with the FDA, the Company now believes that a submission seeking accelerated approval would need to be based on the MRR data from CLOVER-WaM and enrollment in a randomized, controlled confirmatory study that is designed to generate data on progression-free survival (PFS).

"While iopofosine I 131's positive WM data along with the high unmet medical need for these patients support further investment, we have determined that such a program may best be brought to market by a larger organization with greater resources. Importantly, partnering or divesting this program supports our commitment to providing this potentially life-saving drug to the patients who need it as quickly as possible," stated James Caruso, president and CEO of Cellectar. "We believe iopofosine I 131 represents a compelling opportunity as it has shown strong efficacy and good tolerability based on our clinical studies. Moreover, the commercial work we conducted demonstrates iopofosine I 131's substantial market opportunity based upon the product profile, which includes off-the-shelf global distribution, orphan pricing and existing unmet medical need."

Cellectar remains confident in the potential of its phospholipid ether drug conjugate platform and the targeted radiotherapies in its development pipeline. Iopofosine I 131's clinical success validates the platform's ability to target cancers and Cellectar will leverage its experience to focus on the development of its earlier clinical programs.

Specifically, Cellectar will focus on those assets it believes have the highest therapeutic potential and opportunity for value creation. As highlighted by recent acquisitions and collaborations within the radiopharmaceutical sector, precision isotopes like alpha- and Auger-emitters have emerged as the leading therapeutics of interest. Consequently, the Company will now focus its resources on targeting solid tumors by advancing CLR 121225, its actinium-225 based program, and CLR 121125, its iodine-125 Auger-emitting program into the clinic.

Cellectar expects to file Investigational New Drug applications in the first half of 2025 for both CLR-121225 and CLR- 121125, which will allow the initiation of Phase 1 clinical studies in solid tumor cancers. Both programs have demonstrated robust *in vivo* activity, tolerability, excellent targeting and uptake in preclinical solid tumor models. The Company believes this approach will provide an expedited timeframe to achieve safety and proof-of-concept data in patients.

The Company's strategic reprioritization will impact all departments and result in an immediate reduction in headcount of approximately 60%, which should be complete by the end of the fourth quarter 2024. The Company anticipates that the implementation of the restructuring will extend its cash runway into the third quarter of 2025.

"We are being methodical in our efforts to reorganize the company with the goal of conserving cash while maintaining the flexibility to execute immediate priorities and build for long-term growth and value creation. This reorganization is difficult but necessary for the future growth potential of Cellectar," said Mr. Caruso. "I want to extend my deepest gratitude to our departing employees for their significant contributions to our work and their dedication to making a difference in the lives of 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 lead asset, iopofosine I 131, a small-molecule 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, CLR 121125, an iodine-125 Auger-emitting program targeted in other solid tumors, such as triple negative breast, lung and colorectal, proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

In addition, iopofosine I 131 is under evaluation in Phase 2b studies for relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma, alongside 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 Orphan Drug and Fast Track Designations for various cancer indications.

New data from the CLOVER-WaM Phase 2 clinical trial were recently presented in an oral presentation at the 66th American Society of Hematology Annual Meeting and Exposition (ASH 2024).

For more information, please visit www.cellectar.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. 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 obtain regulatory exclusivities, the availability of priority review vouchers, our 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/A for the year ended December 31, 2023, and our Form 10- Q for the quarter ended September 30, 2024. 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

MEDIA:

Christy Maginn
Bliss Bio Health
703-297-7194
cmaginn@blissbiohealth.com

INVESTORS:

Anne Marie Fields
Precision AQ
212-362-1200
annemarie.fields@precisionaq.com

Source: Cellectar Biosciences, Inc.