

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): January 8, 2024

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 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 8.01. Other Events.

On January 8, 2024, the Company issued a press release providing topline data from its Waldenstrom's macroglobulinemia CLOVER-WaM pivotal trial. 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 January 8, 2024, entitled, "Collectar Biosciences Announces Positive Topline Data Achieving Primary Endpoint in Pivotal Clinical Study of Iopofosine I 131 in Waldenstrom's Macroglobulinemia"
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: January 8, 2024

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer



Cellecstar Biosciences Announces Positive Topline Data Achieving Primary Endpoint in Pivotal Clinical Study of Iopofosine I 131 in Waldenstrom's Macroglobulinemia

- *Iopofosine tested in heavily pretreated multi-class refractory population with a median of four prior therapies and achieves 75.6% Overall Response Rate; 61% Major Response Rate (95% CI, 44.5%, 75.8%); 100% Disease Control Rate exceeding protocol statistical hurdle of 20%*
- *Median Duration of Response not yet reached with a median of 8 months follow up*
- *Data continues to mature, anticipate increase in response rates and duration*

FLORHAM PARK, N.J., January 8, 2024 -- Cellecstar 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 announced data from its CLOVER WaM pivotal study, evaluating iopofosine I 131, a potential first-in-class, targeted radiotherapy candidate for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia (WM) patients that have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitors (BTKi). CLOVER WaM is the largest study to date in relapsed or refractory WM patients post-BTKi therapy and represents the most refractory population ever tested in clinical studies based upon a review of published literature.

The CLOVER WaM study met its primary endpoint with a major response rate (MRR) of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]). The overall response rate (ORR) in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and less refractory to multiple classes of drugs. Notably, iopofosine monotherapy achieved an 8% stringent complete remission (sCR) in this highly refractory WM population.

"There is a critical need for new therapies with novel mechanisms of action to treat WM. There are no approved treatments for patients post BTKi therapy, where currently the expected response rate to salvage treatments is approximately 10%, and the expected duration of response in those patients is less than six months," said Sikander Ailawadhi, M.D., professor of medicine at Mayo Clinic, and lead investigator in the CLOVER WaM study. "The results from this pivotal study utilizing just four doses of iopofosine monotherapy in heavily pretreated patients are very compelling, demonstrating deep and durable remissions. The combination of the safety profile and deep durable responses with a high proportion of patients remaining treatment free is impressive."

CLOVER WaM is a single-arm registration study with a target enrollment of 50 patients. The study is fully enrolled and topline safety data is being reported on 45 patients meeting criteria for modified intent to treat (mITT) with a data cut-off date of January 3, 2024. Topline efficacy evaluable population (41) is defined as patients who have received a total administered dose of greater than 60 mCi and had follow up of at least 60 days post last dose. Among mITT patients, median age was 71 years, median IgM level prior to treatment with iopofosine was 2,185, 90% were refractory to either a BTKi (18/36 50%) or anti-CD20 therapy (18/41 40%), with 26.7% multiclass refractory, and 80% of patients were previously treated with a BTKi therapy.

Newton Guerin, International Waldenstrom's Macroglobulinemia Foundation (IWMF) president and CEO, said, "These inspiring topline data represent important and exciting news for the entirety of the WM community battling this challenging disease. WM patients need new, clinically meaningful treatment modalities and currently, there are limited options for patients who have received prior BTKi therapy. Iopofosine's product profile is notable because of its novel mechanism of action, fixed four-dose course of treatment completed within 75 days and the promise of an enhanced quality of life for patients, including a prolonged treatment-free interval."

Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequelae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment related deaths in the study.

"We are most grateful to the patients and their families, participating study sites, their staff and our dedicated employees for the successful completion of this study. Their respective contributions may provide a meaningful new treatment option for patients where there currently are no approved therapies" said James Caruso, president and CEO of Cellecstar. "Iopofosine's high major response rate and achievement of the study's primary endpoint in highly refractory, Waldenstrom's macroglobulinemia patients exhibits its potentially practice-changing clinical profile. We believe the currently impressive response rates and the duration of responses will continue to improve as the data matures. We plan to include these outcomes in our NDA submission and will be requesting an accelerated approval based upon our WM Fast Track Designation."

Conference Call & Webcast Details

Cellecstar management will host a conference call for investors today, January 8, 2024, beginning at 8:00 am ET / 5:00 am PT. Dial-in: 1-888-886-7786. Webcast Link: [Click HERE](#)

About Cellecstar Biosciences, Inc.

Cellecstar 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), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit www.cellecstar.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](#).

About Waldenstrom's Macroglobulinemia

WM is a B-cell malignancy characterized by bone marrow infiltration of 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 10,000 patients require treatment in the relapsed or refractory setting and there are an estimated 4,300 patients requiring 3rd line or greater therapy. There are no FDA approved treatment options for patients progressing on BTKi therapy. BTKi therapies do not demonstrate complete response rates and require continuous treatment. Approximately 50% of 3rd line patients not receiving treatment are likely to consider new treatment options. There is an established unmet need for new FDA approved treatments that provide a novel mechanism of action, increased deep durable responses, and time limited treatment, especially in heavily pretreated WM patients.

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 regarding the WM CLOVER WaM pivotal study. 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, 2022, and our Form 10-Q for the quarter ended September 30, 2023. 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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