

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): July 23, 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
(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 2.02 Results of Operations and Financial Condition.

On July 23, 2024, Collectar Biosciences, Inc. (the "Company") disclosed that the Company had approximately \$25.9 million of cash and cash equivalents as of June 30, 2024.

Because the Company's consolidated financial statements for the quarter ended June 30, 2024 have not been finalized or reviewed, the preliminary statement of the Company's cash and cash equivalents as of June 30, 2024 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of June 30, 2024 may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01 Regulation FD Disclosure.

On July 23, 2024, the Company issued a press release announcing positive results from its ongoing CLOVER WaM pivotal study. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 and 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, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filings.

Item 8.01 Other Events.

On July 23, 2024, the Company announced positive results data from its ongoing CLOVER WaM pivotal study evaluating iopofosine I 131 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”). The data presented was as of an May 31, 2024 data cut.

As of May 31, 2024, results in the CLOVER WaM study had an overall response rate (“ORR”) of 80% and a major response rate (“MRR”) of 56.4% (95% CI, 0.42 to 0.67), which exceeded the agreed-upon primary endpoint of a 20% MRR. Median age was 70 years (range, 50-88) in the modified intent to treat (“mITT”) population (n=55). The median number of prior lines of therapy was 4 (range, 2-14), with approximately 27% of patients refractory to all available therapies (BTKi, anti-CD20 antibody, chemotherapy), and 40% of patients dual-class refractory (BTKi and rituximab). Notably, comparable ORRs were observed across all clinically challenging disease subgroups, including: MYD88-wt (81%; n=16), P53-mutated (80%; n=5), and clinical patient cohorts including post-BTKi (72%; n=39), as well as dual-class (59%; n=22), and triple-class (53%; n=15) refractory patients.

Secondary endpoints of disease control rate (98.2%) and duration of response (“DoR”) presented evidence that iopofosine provided durable clinical benefit across all response categories. The median DoR in patients achieving major response and overall response were not reached as of the data cutoff, with 78% and 72% of patients remaining free from disease progression at 18 months, respectively.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release, dated July 23, 2024
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: July 23, 2024

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



Cellecstar Biosciences' Iopofosine I 131 Exceeds Primary Endpoint in Waldenstrom's Macroglobulinemia Pivotal Study with 78% of Major Response Patients Remaining Progression Free at 18 Months

80% Overall Response Rate Achieved

- **56.4% major response rate exceeded 20% primary endpoint**
- **98.2% disease control rate achieved in heavily pretreated patients**
- **Responses shown in difficult-to-treat, high-needs patient populations with approximately 27% of patients refractory to all available therapies and 40% dual-class refractory (BTKi and rituximab)**

FLORHAM PARK, N.J., July 23, 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 positive results from its CLOVER WaM pivotal study evaluating iopofosine I 131, a potential first-in-class, targeted radiotherapeutic candidate for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia (WM) patients that received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitors (BTKi's). CLOVER WaM is the first and largest WM study to date in a highly refractory patient population, including patients who are refractory to all available treatment categories.

As of May 31, 2024, results in the CLOVER WaM study (NCT02952508) had an overall response rate (ORR) of 80% and a major response rate (MRR) of 56.4%(95% CI, 0.42 to 0.67), which exceeded the agreed-upon primary endpoint of a 20% MRR. Median age was 70 years (range, 50-88) in the modified intent to treat (mITT) population (n=55). The median number of prior lines of therapy was 4 (range, 2-14), with approximately 27% of patients refractory to all available therapies (BTKi, anti-CD20 antibody, chemotherapy), and 40% of patients dual-class refractory (BTKi and rituximab). Notably, comparable ORRs were observed across all clinically challenging disease subgroups, including: MYD88-wt (81%; n=16), P53-mutated (80%; n=5), and clinical patient cohorts including post-BTKi (72%; n=39), as well as dual-class (59%; n=22), and triple-class (53%; n=15) refractory patients.

"Treatment options for relapsed or refractory WM patients are limited with a critical need for new therapies with novel mechanisms of action. Currently, only about 10% of patients receiving salvage therapy respond to that treatment and experience limited durability of less than six months in later lines of therapy," said Sikander Ailawadhi, M.D., professor of medicine at Mayo Clinic, and lead investigator in the CLOVER WaM study. "The 98% disease control rate and 80% ORR achieved in this pivotal study utilizing just four doses of iopofosine monotherapy in multi-class refractory patients are very compelling, demonstrating impressive deep and durable responses with a high proportion of patients remaining treatment-free."

Secondary endpoints of disease control rate (98.2%) and duration of response (DoR) presented evidence that iopofosine provided durable clinical benefit across all response categories. The median DoR in patients achieving major response and overall response were not reached as of the data cutoff, with 78% and 72% of patients remaining free from disease progression at 18 months, respectively.

"The outcomes observed in this study continue to far exceed expectations and provide evidence of the potential for iopofosine in a broad range of WM patients, including difficult-to-treat subgroups. We believe with these results that iopofosine I 131 has the potential to become the standard-of-care therapy for relapsed/refractory patients," said James Caruso, president and CEO of Cellecstar. "It is our commitment to ensure that iopofosine will be made available to patients awaiting a meaningful new treatment option. To this end, we plan to submit our NDA in the fourth quarter of 2024 and will be seeking priority review, which provides an estimated six-month regulatory review period."

Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the company's previously reported safety data. Importantly, and unlike other cancer therapies, patients on iopofosine did not experience any cardiovascular, renal, or liver toxicities, and no peripheral neuropathy or significant bleeding. The safety profile was consistent with selective targeting of tumor sites with clinically negligible off-target effect outside the hematologic system. The most commonly reported treatment emergent adverse events were hematologic in nature (thrombocytopenia, neutropenia and anemia) and were predictable and manageable. All patients recovered from cytopenias within a few weeks post nadir.

*Iopofosine I 131 is an investigational agent and has not been approved for use in any country, for any indication.

Conference Call & Webcast

The company will host an event on July 24, 2024, at 8:00 a.m., EDT, to provide a comprehensive overview of the CLOVER WaM study data, the current WM treatment landscape, unmet needs for patients with this disease, and opportunities to improve patient outcomes.

The event will feature both company leadership and key investigators. Details are as follows:

Conference Call Details

Date: July 24, 2024
Time: 8:00 a.m. EDT/ 5:00 a.m. PDT
Dial-in number: 1-800-717-1738
Webcast link: [click HERE](#)

A replay of the conference call will be available on theEvents section of the company's investor relations website.

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 11,500 patients require treatment in the relapsed or refractory setting and there are an estimated 4,700 patients requiring 3rd line or greater therapy. There are approximately 1,000 patients that have exhausted all current treatment options by 3rd line because they are ineligible or intolerant to those existing therapies. Therefore, the total addressable market for 3rd line or greater therapy is approximately 5,700 patients. 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 because greater than 50% of patients are treated with the same or similar treatment from prior lines of therapy. Greater than 60% of treatments utilized are non-FDA approved therapies. 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.

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

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 including our expectations regarding the CLOVER WaM pivotal trial. 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's review process and view of our data, 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, 2023, and our Form 10-Q for the quarter ended March 31, 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.

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