

**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 13, 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 2.02. Results of Operations and Financial Condition.

On August 13, 2024, we issued a press release announcing our financial results for the quarter ended June 30, 2024 and provided a corporate update. 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 13, 2024, titled "Collectar Biosciences Reports Financial Results for Q2 2024 and Provides a Corporate Update"
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: August 13, 2024

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

Collectar Biosciences Reports Financial Results for Q2 2024 and Provides a Corporate Update

Management to host a conference call today at 8:30 am ET

FLORHAM PARK, N.J., August 13, 2024 – Collectar 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 financial results for the quarter ended June 30, 2024, and provided a corporate update.

“With our recent positive data announcement from the CLOVER WaM pivotal study evaluating iopofosine I 131 in Waldenstrom’s macroglobulinemia, we remain focused on filing our WM NDA in the fourth quarter of this year,” said James Caruso, president and CEO of Collectar. “We anticipate an accelerated six-month NDA review period and continue to prepare for a potential launch of iopofosine in 2025. We look forward to bringing this meaningful therapy to market and establishing iopofosine I 131 as the standard of care for the treatment of relapsed and refractory WM patients.”

Second Quarter and Recent Corporate Highlights

- Announced final data exceeded the primary endpoint in the company’s 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). Data from the pivotal study demonstrated an 80% overall response rate (ORR), and a 56.4% major response rate (MRR) which exceeded the agreed-upon primary endpoint of a 20% MRR. 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 iopofosine I 131 ORRs were observed across all clinically challenging disease subgroups, including: MYD99-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% of major response patients and 72% of overall response patients remaining free from disease progression at 18 months, respectively.
- Announced a strategic partnership with City of Hope Cancer Center, one of the largest cancer research and treatment organizations in the United States, to evaluate iopofosine I 131 in mycosis fungoides, a rare form of non-Hodgkin’s lymphoma (NHL) that affects the skin and, in some patients, internal organs and blood. The investigator-sponsored trial will evaluate approximately 10 patients with initiation planned for late 2024 or early 2025.

Second Quarter 2024 Financial Highlights

- Cash and Cash Equivalents:** As of June 30, 2024, the company had cash and cash equivalents of \$25.9 million, compared to \$9.6 million as of December 31, 2023. Net cash used in operating activities during the three months ended June 30, 2024, was approximately \$14.1 million. The company believes its cash balance as of June 30, 2024, when combined with the \$19.4 million raised in July, is adequate to fund its basic budgeted operations into the second quarter of 2025.
- Research and Development Expense:** R&D expense for the three months ended June 30, 2024, was approximately \$8.2 million, compared to approximately \$6.3 million for the three months ended June 30, 2023. The overall increase in R&D was primarily a result of expenditures for the company’s WM pivotal trial, in addition to investments in product sourcing, manufacturing, and logistics infrastructure.
- General and Administrative Expense:** G&A expense for the three months ended June 30, 2024, was \$6.4 million, compared to \$2.0 million for the same period in 2023. The increase in G&A was primarily driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related marketing and personnel costs.

Conference Call & Webcast Details

Collectar management will host a conference call for investors today, August 13, 2024, beginning at 8:30 am Eastern Time to discuss these results and answer questions. Stockholders and other interested parties may participate in the conference call by dialing 1-800-717-1738. The call will be available via webcast by [clicking HERE](#) or on the [Events](#) page of the company’s website.

About Collectar Biosciences, Inc.

Collectar 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.collectar.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 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, 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.

Contacts

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