
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 14, 2025

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 14, 2025, we issued a press release announcing our financial results for the quarter ended June 30, 2025, 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
<u>99.1</u>	<u>Press release dated August 14, 2025, titled “Celectar Biosciences Reports Second Quarter 2025 Financial Results and Provides a Corporate Update”</u>
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 14, 2025

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer



Collectar Biosciences Reports Second Quarter 2025 Financial Results and Provides a Corporate Update

Intend to Pursue an NDA Submission to the U.S. FDA under Accelerated Approval Pathway for Iopofosine I 131 for the Treatment of Waldenstrom Macroglobulinemia (WM) Subject to Sufficient Funding and Once the Confirmatory Trial is Underway

Continue to Work with the EMA Toward a Potential Submission of Iopofosine I 131 for Conditional Approval in the EU; Decision expected late 3Q early 4Q 2025

On track to advance CLR 125 into Phase 1 TNBC trial 4Q 2025

Company to Hold Webcast and Conference Call at 8:30 AM ET Today

FLORHAM PARK, N.J., August 14, 2025 (GLOBE NEWSWIRE) -- Collectar 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 financial results for the quarter ended June 30, 2025, and provided a corporate update on its promising portfolio of clinical and pre-clinical radiopharmaceutical therapeutics.

Second Quarter and Subsequent Corporate Highlights

- Announces plans to pursue an NDA submission to the FDA for the accelerated approval of iopofosine I 131 as a treatment for WM subject to sufficient funding and once the confirmatory trial is underway
 - o The submission would be supported by data from the Phase 2b CLOVER WaM clinical trial demonstrating 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 Bruton Tyrosine Kinase inhibitor (BTKi) treatment failures regardless of line of therapy.
 - o The Company plans to share these new data at an upcoming medical or scientific conference.
 - Granted FDA Breakthrough Therapy Designation for iopofosine I 131, a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether as a radioconjugate monotherapy, for the treatment of relapsed/refractory WM.
 - Received the EMA response regarding scientific advice on its submission for Conditional Market Authorization (CMA) and continues to work with the EMA toward a potential submission.
 - o The submission to EMA included data from the Phase 2b CLOVER WaM clinical trial where the company observed a statistically significant major response rate, meaningful duration of response and integrated summary of safety for all patients treated with iopofosine I 131 for hematologic malignancies.
 - o Scheduled a follow-up meeting with the EMA and expect to make a final decision to submit for a CMA late in the third quarter or early in the fourth quarter of 2025.
 - Submitted a trial protocol with the FDA for a Phase 1b Dose Finding study of our Auger-emitting radiopharmaceutical, CLR 125, for the treatment of relapsed TNBC. CLR 125 is an iodine-125 Auger-emitting drug candidate targeting solid tumors, such as triple negative breast, lung and colorectal cancers.
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- Reported a positive initial data update from the Phase 1 clinical trial of iopofosine I 131 in pediatric patients with relapsed/refractory high-grade glioma (pHGG).
 - o All patients receiving a minimum of 55 mCi total administered dose (n=7) experienced an average of 5.4 months of progression free survival (PFS) and 8.6 months of overall survival (OS), ongoing.
 - o All patients experienced disease control, which correlates with survival benefit.
 - o Three patients who received additional dosing cycles (a minimum of four total infusions) had an average PFS of 8.1 months and an OS of 11.5 months (ranging from 4.9 to 14.9 months), ongoing, with two achieving an objective response.
- In active discussions with multiple potential partners for the regional or global licensing of iopofosine I 131 which are designed to provide funding to support the submission of an NDA for accelerated approval and the required confirmatory study.
- Entered a long-term multi-isotope supply agreement with Nusano to provide Cellestar with iodine-125 and actinium-225 for its clinical studies and future commercial needs.
- Raised nearly \$9.5 million through separate June and July 2025 financings. Funds from these financings will be used to advance the Company's next-generation pipeline of radiopharmaceuticals in solid tumors into the clinic and to continue regulatory engagement and partnership discussions for iopofosine I 131.

"Throughout the first half of 2025 we made meaningful progress advancing our pipeline of targeted radiopharmaceuticals and are entering the second half with solid momentum and a clear plan," said James Caruso, president and CEO of Cellestar. We are encouraged by the recent FDA Breakthrough Therapy Designation and the totality of compelling CLOVER WaM safety and efficacy data. Importantly, our regulatory strategy aligns with the FDA's recently stated mission to accelerate the delivery of lifesaving medicines to patients battling rare diseases, such as WM."

"We continue our interactions with the European Medicines Agency (EMA) and are hopeful that they will recommend that we file for a fast-track, conditional marketing authorization approval. We expect their decision either late third or early in the fourth quarter of 2025. In parallel, we remain in active discussions with multiple potential partners to support the NDA filing for accelerated approval of iopofosine I 131 for the treatment of WM. Currently, we view sufficient funding or collaborations as a precursor to the confirmatory study initiation and submission of an NDA for accelerated approval. Such partnerships may provide non-dilutive capital that preserves stockholder value and could potentially accelerate our path to commercialization across key global markets."

"Beyond iopofosine, we are making tremendous headway advancing our next-generation pipeline of radiopharmaceuticals targeting solid tumors, such as triple-negative breast cancer (TNBC) and pancreatic cancer. We plan to advance CLR 125 into the clinic by late 2025 or early 2026. The FDA has received our Phase 1 protocol submission for the CLR 125 program. We are excited by the opportunities Cellestar possesses to bring transformative radiopharmaceutical therapies to patients in need and look forward to achieving value-creating milestones throughout the balance of the year and beyond," concluded Mr. Caruso.

Second Quarter 2025 Financial Highlights

- **Cash and Cash Equivalents:** As of June 30, 2025, the company had cash and cash equivalents of approximately \$11.0 million, compared to \$23.3 million as of December 31, 2024, which includes \$2.3 million in net proceeds received in connection with the company's June warrant exercises but does not reflect net proceeds of approximately \$5.8 million from the July 2025 offering. The company believes its cash balance as of June 30, 2025, inclusive of the additional funds raised in July, is adequate to fund its basic budgeted operations into the second quarter of 2026.
- **Research and Development Expenses:** R&D expenses for the three months ended June 30, 2025, were approximately \$2.4 million, compared to approximately \$7.3 million for the three months ended June 30, 2024. The overall lower expense was primarily driven by decreased clinical project costs and manufacturing and related costs resulting from the conclusion of patient enrollment in our CLOVER WaM Phase 2b clinical trial.
- **General and Administrative Expenses:** G&A expenses for the three months ended June 30, 2025, were approximately \$3.6 million, compared to approximately \$6.4 million for the same period in 2024. The reduction was the result of decreased commercialization activities and personnel costs.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended June 30, 2025, was \$5.4 million, or \$3.39 per primary and diluted share, compared to \$0.9 million, or \$0.77 per primary share and \$5.43 per diluted share in the three months ended June 30, 2024.

Conference Call & Webcast Details

Collectar management will host a conference call and webcast today, August 14, 2025, 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. A live webcast of the conference call can be accessed in the "Events & Presentations" section of Collectar's website at www.collectar.com. A recording of the webcast will be available and archived on the company's website for approximately 90 days.

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 its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope); CLR 121125, an iodine-125 Auger-emitting program targeted in other solid tumors, such as triple negative breast, lung and colorectal; CLR 121225, an actinium-225 based program being targeted to several solid tumors with significant unmet need, such as pancreatic cancer; and 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 Collectar 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.collectar.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 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.

INVESTORS:

Anne Marie Fields

Precision AQ

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+++ TABLES TO FOLLOW +++



CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 11,041,027	\$ 23,288,607
Prepaid expenses and other current assets	1,576,579	961,665
Total current assets	12,617,606	24,250,272
Property, plant & equipment, net	647,549	757,121
Operating lease right-of-use asset	400,248	436,874
Other long-term assets	29,780	29,780
TOTAL ASSETS	\$ 13,695,183	\$ 25,474,047
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 4,678,713	\$ 7,585,340
Warrant liability	1,095,926	1,718,000
Lease liability, current	92,022	84,417
Total current liabilities	5,866,661	9,387,757
Lease liability, net of current portion	361,487	409,586
TOTAL LIABILITIES	6,228,148	9,797,343
COMMITMENTS AND CONTINGENCIES (Note 7)		
MEZZANINE EQUITY:		
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of June 30, 2025 and December 31, 2024	1,382,023	1,382,023
STOCKHOLDERS' EQUITY (DEFICIT):		
Series E-2 preferred stock, 1,225 shares authorized; 35.60 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	520,778	520,778
Common stock, \$0.00001 par value; 170,000,000 shares authorized; 1,812,040 and 1,535,996 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	18	15
Additional paid-in capital	264,958,619	261,116,351
Accumulated deficit	(259,394,403)	(247,342,463)
Total stockholders' equity (deficit)	6,085,012	14,294,681
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 13,695,183	\$ 25,474,047



CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
OPERATING EXPENSES:				
Research and development	\$ 2,389,801	\$ 7,345,480	\$ 5,816,896	\$ 14,433,523
General and administrative	3,647,728	6,358,229	6,621,624	11,271,673
Total operating expenses	6,037,529	13,703,709	12,438,520	25,705,196
LOSS FROM OPERATIONS	(6,037,529)	(13,703,709)	(12,438,520)	(25,705,196)
OTHER INCOME (EXPENSE):				
Gain (loss) on valuation of warrants	501,598	12,455,431	161,598	(2,504,915)
Interest income	88,020	328,907	224,982	648,756
Total other income (expense)	589,618	12,784,338	386,580	(1,856,159)
NET LOSS	\$ (5,447,911)	\$ (919,371)	\$ (12,051,940)	\$ (27,561,355)
NET LOSS PER SHARE — BASIC	\$ (3.39)	\$ (0.77)	\$ (7.66)	\$ (25.38)
NET LOSS PER SHARE — DILUTED	\$ (3.39)	\$ (5.43)	\$ (7.66)	\$ (25.38)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	1,608,799	1,193,981	1,572,598	1,086,102
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	1,608,799	1,248,210	1,572,598	1,086,102