

Securities registered pursuant to Section 12(b) of the Act:

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2025, we issued a press release announcing our financial results for the quarter ended September 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 November 13, 2025, titled “Cellestar Biosciences Reports Third Quarter 2025 Financial Results and Provides 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: November 13, 2025

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer



Cellecstar Biosciences Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Expects to Submit Conditional Marketing Approval Application in Europe for Iopofosine I 131 in Refractory (post-BTKi) Waldenstrom's Macroglobulinemia in 2026 Following Advice and Guidance from Scientific Advice Working Party (SAWP)

Initiated Phase 1b Study of CLR 125 for TNBC

Received Rare Pediatric Drug Designation for Iopofosine I 131 in Inoperable Relapsed/Refractory Pediatric High-Grade Glioma (r/r pHGG)

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

FLORHAM PARK, N.J., November 13, 2025 (GLOBE NEWSWIRE) -- Cellecstar 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 September 30, 2025, and provided a corporate update.

"Our productive engagement with the European Medicines Agency (EMA) highlighted by confirmation of eligibility to submit for a conditional marketing authorization marks a significant step forward in our global regulatory strategy, bringing us closer to potential approval and commercialization of iopofosine I-131 for WM in 2027. In parallel, additional data from the CLOVER WaM study and the receipt of breakthrough designation from the FDA continues to support a path toward a New Drug Application for accelerated approval," stated James Caruso, president and CEO of Cellecstar. "We believe this regulatory pathway, combined with the compelling clinical results we've seen to date, reinforces the value of iopofosine and positions it as a highly attractive asset for collaboration or strategic partnership.

"Looking ahead, we are excited to further advance our promising radioconjugate pipeline of auger- and alpha-emitting drug candidates and have initiated a Phase 1b trial for CLR 125 in triple-negative breast cancer, which builds on strong preclinical data showing reduction or inhibition of solid tumor growth. We are also progressing our early-stage asset, CLR 225, which has shown robust anti-tumor activity in pancreatic cancer models, and has recently completed IND-enabling studies. Each of these achievements brings us closer to our goal of transforming the outlook for patients facing aggressive and life-threatening cancers," concluded Mr. Caruso.

Third Quarter and Subsequent Corporate Highlights

- Advised by the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) that filing for a Conditional Marketing Approval (CMA) for iopofosine I 131 as a treatment for post-Bruton Tyrosine Kinase inhibitor (BTKi) refractory patients with Waldenstrom macroglobulinemia (WM) could be acceptable for CMA.
- Plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the accelerated approval of iopofosine I 131 as a treatment for WM once the confirmatory trial is underway, which is subject to sufficient funding.
 - o The Phase 3 study for iopofosine I 131, a potentially first-in-class, targeted radiotherapeutic candidate for the treatment of relapsed/refractory WM will be a comparator, randomized controlled study with approximately 100 patients per arm with full patient enrollment projected within 18-24 months of the first patient admitted to the study.

- The Company has received clearance for its Investigational New Drug application for CLR 125, the Company's lead Auger-emitting (iodine-125) PRC for a Phase 1b/2a dose finding study in triple-negative breast cancer. CLR 125 provides the greatest precision in targeted radiotherapy as emissions only travel a few nanometers.
 - o The Company announced a partnership with Evestia Clinical to provide CRO services to support their upcoming Phase 1b study evaluating CLR 125 for the treatment of triple-negative breast cancer (TNBC).
- Received rare pediatric drug designation (RPDD) for iopofosine I 131 in inoperable relapsed or refractory pediatric high-grade glioma (r/r pHGG).
 - o Interim data from the Phase 1b dose and optimization study, CLOVER-2, was highlighted in an oral presentation at the American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer. Results showed extended progression-free survival along with overall survival, and iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data.
- Presented preclinical data from CLR 121225 (CLR 225), a novel actinium-based radio conjugate alpha-emitter for treatment of hypoxic pancreatic ductal adenocarcinoma (PDAC) at the American Association for Cancer Research (AACR) Special Conference on Pancreatic Cancer Research. In three separate pancreatic cancer xenograft models, CLR 225 demonstrated inhibition of tumor growth or reduction in tumor volume, dependent on dose, with potential survival benefit following treatment.
 - o The Company has entered into a supply agreement with ITM Isotope Technologies Munich (ITM) for Actinium-225 (Ac-225), which will support clinical development of Cellecstar's actinium-labeled compound CLR 225.
 - o CLR 225 has completed the required Investigational New Drug (IND)-enabling studies and the company maintains the option to move into a Phase 1 study. Previous data from CLR 225 has demonstrated activity in multiple solid tumor animal models, including pancreatic, colorectal and breast cancer.
- Raised approximately \$12.7 million. These funds will be used to advance the Company's TNBC study and to complete the EMA Conditional Marketing Authorization application for iopofosine I 131 for WM.

Third Quarter 2025 Financial Highlights

- **Cash and Cash Equivalents:** As of September 30, 2025, the company had cash and cash equivalents of \$12.6 million, compared to \$23.3 million as of December 31, 2024. The company believes its cash balance as of September 30, 2025, is adequate to fund its budgeted operations into the third quarter of 2026. Following the close of the third quarter in October 2025, several institutional investors exercised certain existing warrants for gross proceeds to the company of approximately \$5.8 million prior to deducting placement agent fees and estimated offering expenses.
 - **Research and Development Expenses:** R&D expenses for the three months ended September 30, 2025, were approximately \$2.5 million, compared to approximately \$5.5 million for the three months ended September 30, 2024. The overall decrease was primarily a result of reduced clinical trial costs.
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- **General and Administrative Expenses:** G&A expenses for the three months ended September 30, 2025, were approximately \$2.3 million, compared to approximately \$7.8 million for the same period in 2024. The decrease was primarily driven by lower commercialization and personnel costs.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended September 30, 2025, was \$4.4 million, or \$1.41 per basic and diluted share, compared to a net loss of \$14.7 million, or \$11.18 per basic and \$12.13 per diluted share in the three months ended September 30, 2024.

Conference Call & Webcast Details

Cellecstar management will host a conference call and webcast today, November 13, 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 Cellecstar’s website at www.cellecstar.com. A recording of the webcast will be available and archived on the Company’s website for approximately 90 days.

About Cellecstar Biosciences, Inc.

Cellecstar Biosciences is a late-stage clinical radiopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer. 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 that deliver improved efficacy and better safety.

The company’s product pipeline includes its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope) for the treatment of hematologic and solid tumor cancers such as Waldenström’s macroglobulinemia (WM) and pediatric high grade gliomas; CLR 121125, an iodine-125 Auger-emitting program targeting solid tumors, such as triple negative breast, lung and colorectal cancers; CLR 121225, an actinium-225 based program targeting solid tumors with significant unmet need, such as pancreatic cancer; and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

Iopofosine I 131 has been studied in Phase 2b trials for relapsed or refractory WM and multiple myeloma (MM), non-Hodgkin’s lymphomas and central nervous system (CNS) lymphoma, and the CLOVER-2 Phase 1b study, targeting pediatric patients with high-grade gliomas, for which Cellecstar is eligible to receive a Pediatric Review Voucher from the FDA upon approval. The FDA has granted iopofosine I 131 Breakthrough Therapy, six Orphan Drug, five Rare Pediatric Drug and two Fast Track Designations for various cancer indications. The European Medicines Agency (EMA) has also granted PRIME and orphan drug designations for the treatment of WM.

For more information, please visit www.cellecstar.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 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 ended September 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:

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 12,554,289	\$ 23,288,607
Prepaid expenses and other current assets	1,067,409	961,665
Total current assets	13,621,698	24,250,272
Property, plant & equipment, net	595,271	757,121
Operating lease right-of-use asset	380,841	436,874
Other long-term assets	29,780	29,780
TOTAL ASSETS	\$ 14,627,590	\$ 25,474,047
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 4,014,682	\$ 7,585,340
Warrant liability	801,650	1,718,000
Lease liability, current	96,034	84,417
Total current liabilities	4,912,366	9,387,757
Lease liability, net of current portion	335,895	409,586
TOTAL LIABILITIES	5,248,261	9,797,343
COMMITMENTS AND CONTINGENCIES (Note 7)		
MEZZANINE EQUITY:		
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of September 30, 2025 and December 31, 2024	1,382,023	1,382,023
STOCKHOLDERS' EQUITY:		
Series E-2 preferred stock, 1,225 shares authorized; 35.60 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	520,778	520,778
Common stock, \$0.00001 par value; 170,000,000 shares authorized; 3,192,040 and 1,535,996 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	32	15
Additional paid-in capital	271,314,776	261,116,351
Accumulated deficit	(263,838,280)	(247,342,463)
Total stockholders' equity	7,997,306	14,294,681
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 14,627,590	\$ 25,474,047

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
OPERATING EXPENSES:				
Research and development	\$ 2,523,305	\$ 5,493,496	\$ 8,340,200	\$ 19,927,019
General and administrative	2,327,391	7,834,181	8,949,015	19,105,853
Total operating expenses	4,850,696	13,327,677	17,289,215	39,032,872
LOSS FROM OPERATIONS	(4,850,696)	(13,327,677)	(17,289,215)	(39,032,872)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	—	(7,743,284)	—	(7,743,284)
Gain (loss) on valuation of warrants	294,276	6,088,355	455,874	3,583,440
Interest income	112,543	317,887	337,525	966,643
Total other income (expense)	406,819	(1,337,042)	793,399	(3,193,201)
NET LOSS	\$ (4,443,877)	\$ (14,664,719)	\$ (16,495,816)	\$ (42,226,073)
NET LOSS PER SHARE — BASIC	\$ (1.41)	\$ (11.18)	\$ (7.82)	\$ (36.35)
NET LOSS PER SHARE — DILUTED	\$ (1.41)	\$ (12.13)	\$ (7.82)	\$ (41.79)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	3,162,040	1,311,197	2,108,234	1,161,681
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	3,162,040	1,326,474	2,108,234	1,184,850