

March 13, 2025



Cellestar Biosciences Reports Financial Results for Year Ended 2024 and Provides a Corporate Update

Achieves alignment with U.S. Food and Drug Administration (FDA) on regulatory path for potential accelerated approval of iopofosine I 131 as a treatment for Waldenström macroglobulinemia (WM)

Evaluating timing for Phase 1 solid tumor studies; Auger-emitting radioconjugate prepared for Phase 1b; plans to submit an IND for alpha-emitting radioconjugate;

Company to host webcast and conference call at 8:30 AM ET today

FLORHAM PARK, N.J., March 13, 2025 (GLOBE NEWSWIRE) -- Cellestar 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 year ended December 31, 2024, and provided a corporate update.

“In 2024 the company showcased the efficacy and safety of iopofosine I 131 for the treatment of relapsed/refractory Waldenström macroglobulinemia. We recently completed a productive meeting with the FDA that established a clear regulatory pathway for the accelerated approval of this promising drug. Based upon this regulatory clarity, the quality of the CLOVER-WaM data, and a robust global market opportunity, we continue to evaluate inbound inquiries regarding a range of collaborations for iopofosine I 131, which we view as an attractive, non-dilutive funding approach.” said James Caruso, president and CEO of Cellestar. “In addition, the company received clearance for an IND for our Auger-emitting radioconjugate and will be submitting an IND application for our alpha-emitting radioconjugate. By the middle of 2025 we will be prepared to advance into phase 1 clinical studies for both compounds, in triple negative breast cancer and pancreatic cancer indications, respectively.”

2024 and Recent Corporate Highlights

- Finalized confirmatory study design and regulatory pathway for potential FDA accelerated approval of iopofosine I 131, the Company’s targeted radiotherapeutic candidate for the treatment of relapsed/refractory WM.
 - The study will be a randomized, controlled trial of iopofosine I 131 versus a comparator arm, with 100 patients per arm.
 - Two-stage approval process includes conditional accelerated approval based on a major response rate (MRR) endpoint with full approval based upon achieving a progression-free survival endpoint.

- Company expects to complete full patient enrollment within 24 months of the first patient admitted to the study.
- Total study cost is expected to be between \$40M-\$45M, with approximately \$30M to full enrollment.
- Presented data from the Phase 2 CLOVER-WaM study in an oral session at the 66th American Society of Hematology Annual Meeting and Exposition (ASH 2024) in December. The oral presentation highlighted that treatment with iopofosine I 131 in patients suffering from relapsed/refractory WM demonstrated:
 - overall Response Rate (ORR) was 83.6%;
 - major Response Rate (MRR) was 58.2%, which exceeded the FDA agreed-upon primary endpoint of 20% MRR;
 - durable efficacy in previously treated WM patients, with no current standard of care therapy;
 - well tolerated with a manageable toxicity profile across broad biologic and clinical subgroups.
- An article published in the journal eBioMedicine, volume 111, 2025, 105496, ISSN 2352-3964 from a SPORE Grant-supported, investigator-led study utilizing iopofosine I 131 (also known as CLR 131) in combination with external beam radiation, reported the best overall response from 11 evaluable patients included seven participants with a complete response (63.6%), one with a partial response (9%), one with stable disease (9%), and two with disease progression (18%), further supporting iopofosine I 131's therapeutic benefit in solid tumors.
- Continued development of CLR 121225 and CLR 121125, the Company's pre-clinical radioconjugate assets, to support Phase 1 solid tumor studies:
 - The company is prepared to initiate a Phase 1b/2a dose-finding study with CLR 121125 in triple-negative breast cancer. CLR 121125 is the company's lead Auger-emitting (iodine-125) Phospholipid Radioconjugate™ (PRC) that provides the greatest precision in targeted radiotherapy as emissions only travel a few nanometers.
 - The company plans to file an IND application in the first half of 2025 for CLR 121225. CLR 121225 is Cellectar's lead alpha-emitting (actinium-225) PRC, which has demonstrated activity in multiple solid tumor animal models, including pancreatic and colorectal cancer.

2024 Financial Highlights

- **Cash and Cash Equivalents:** As of December 31, 2024, the company had cash and cash equivalents of \$23.3 million, compared to \$9.6 million as of December 31, 2023. In 2024, Cellectar executed multiple financial transactions, including investors' exercise of warrants in January 2024 that generated \$44.1 million, and an inducement financing in July 2024, which included the exercise of existing warrants and the purchase of new warrants for an additional \$19.4 million. The company believes its cash balance as of December 31, 2024, is adequate to fund its basic budgeted operations into the fourth quarter of 2025.
- **Research and Development Expenses:** R&D expenses for the year ended December 31, 2024, were approximately \$26.1 million, compared to approximately \$27.3 million for the year ended December 31, 2023. The decrease was primarily a

result of the timing of expenditures for our WM Phase 2 study to support final patient visits, partially offset by the extensive analytic work necessary to prepare for a planned regulatory submission, product sourcing, manufacturing, and logistics infrastructure costs to support multi sourcing for each aspect of iopofosine I 131 production.

- **General and Administrative Expenses:** G&A expenses for the year ended December 31, 2024, were approximately \$25.6 million, compared to approximately \$11.7 million for the same period in 2023. The increase was primarily driven by costs associated with the development of infrastructure necessary to support potential commercialization, including the related marketing and personnel costs.
- **Other income and expense:** Other income and expense, net, was approximately \$7.3 million of income in 2024, as compared to approximately \$3.9 million of expense in the prior year. These amounts are almost exclusively non-cash and driven by the issuance and valuation of equity securities in conjunction with financing activities. The only cash impact was interest income, which for 2024 improved to approximately \$1.2 million from \$0.4 million in the prior year.
- **Net Loss:** Net loss for the full year ending December 31, 2024, was \$44.6 million or \$1.22 per basic share and \$1.40 per diluted share, compared with \$42.8 million or \$3.50 per basic and diluted share during 2023.

Conference Call & Webcast Details

Cellectar management will host a conference call and webcast today, March 13, 2024, 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 Cellectar’s website at www.cellectar.com. A recording of the webcast will be available and archived on the Company’s website for approximately 90 days.

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

INVESTORS:

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CELLECTAR BIOSCIENCES, INC. CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 23,288,607	\$ 9,564,988
Prepaid expenses and other current assets	961,665	888,225
Total current assets	24,250,272	10,453,213
Property, plant & equipment, net	757,121	1,090,304
Operating lease right-of-use asset	436,874	502,283
Other long-term assets	29,780	29,780
TOTAL ASSETS	<u>\$ 25,474,047</u>	<u>\$ 12,075,580</u>

LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY

CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 7,585,340	\$ 9,178,645
Warrant liability	1,718,000	16,120,898
Lease liability, current	84,417	58,979
Total current liabilities	<u>9,387,757</u>	<u>25,358,522</u>
Lease liability, net of current portion	409,586	494,003
TOTAL LIABILITIES	<u>9,797,343</u>	<u>25,852,525</u>
COMMITMENTS AND CONTINGENCIES (Note 10)		
MEZZANINE EQUITY:		
Series D convertible preferred stock, 111.11 shares authorized; 111.11 shares issued and outstanding as of December 31, 2024 and 2023	1,382,023	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:		
Series E-2 preferred stock, 1,225.00 shares authorized; 35.60 and 319.76 shares issued and outstanding as of December 31, 2024 and 2023, respectively	520,778	4,677,632
Common stock, \$0.00001 par value; 170,000,000 shares authorized; 46,079,875 and 20,744,110 shares issued and outstanding as of December 31, 2024 and 2023, respectively	461	207
Additional paid-in capital	261,115,905	182,924,210
Accumulated deficit	(247,342,463)	(202,761,017)
Total stockholders' (deficit) equity	<u>14,294,681</u>	<u>(15,158,968)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	<u>\$ 25,474,047</u>	<u>\$ 12,075,580</u>

CELLECTAR BIOSCIENCES, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2024	2023
OPERATING EXPENSES:		
Research and development	\$ 26,136,246	\$ 27,266,276
General and administrative	25,641,452	11,694,367
Total operating expenses	<u>51,777,698</u>	<u>38,960,643</u>
LOSS FROM OPERATIONS	<u>(51,777,698)</u>	<u>(38,960,643)</u>
OTHER INCOME (EXPENSE):		
Warrant issuance expense	(7,743,284)	(470,000)

Gain (loss) on valuation of warrants	13,794,683	(3,787,114)
Interest income	1,210,853	387,147
Total other income (expense), net	7,262,252	(3,869,967)
LOSS BEFORE INCOME TAXES	(44,515,446)	(42,830,610)
INCOME TAX PROVISION (BENEFIT)	66,000	(60,000)
NET LOSS	<u><u>\$(44,581,446)</u></u>	<u><u>\$(42,770,610)</u></u>
NET LOSS PER SHARE — BASIC	<u><u>\$ (1.22)</u></u>	<u><u>\$ (3.50)</u></u>
NET LOSS PER SHARE — DILUTED	<u><u>\$ (1.40)</u></u>	<u><u>\$ (3.50)</u></u>
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	<u><u>36,622,474</u></u>	<u><u>12,221,571</u></u>
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	<u><u>37,143,769</u></u>	<u><u>12,221,571</u></u>



Source: Cellestar Biosciences, Inc.