

May 14, 2024



Cellecstar Biosciences Reports Financial Results for Q1 2024 and Provides a Corporate Update

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

WM pivotal study data to be announced in June

FLORHAM PARK, N.J., May 14, 2024 (GLOBE NEWSWIRE) -- 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 financial results for the quarter ended March 31, 2024, and provided a corporate update.

“We plan to announce data from our CLOVER WaM pivotal study evaluating iopofosine I 131 in Waldenstrom’s macroglobulinemia in June and are on track to submit our NDA in the second half of 2024. We remain pleased with patient enrollment in the phase 1b pediatric high-grade glioma study and expect to announce data in the second half of 2024,” said James Caruso, president, and CEO of Cellecstar. “Either alone or in collaboration, we continue to assess the versatility of our delivery platform with a wide range of cancer targeting compounds including peptides, oligos and our alpha-emitting phospholipid radiotherapeutic conjugate, CLR 121225, which is planned to enter a phase 1 study in either triple negative breast or pancreatic cancer no later than first quarter 2025.”

First Quarter and Recent Corporate Highlights

- Announced positive topline data achieving its primary endpoint in its CLOVER WaM pivotal study, evaluating iopofosine I 131, a potentially first-in-class, targeted radiotherapy candidate for the treatment of relapsed/refractory Waldenstrom’s macroglobulinemia (WM) patients with a median of four prior lines of therapy. The CLOVER WaM study met its primary endpoint with a major response rate of 61%. The overall response rate was 75.6%. The Company plans to announce data for all evaluable patients in June 2024.
- Reported a complete remission rate of 64% and overall response rate of 73% in highly refractory patients in an investigator-initiated Phase I study of iopofosine in combination with External Beam Radiotherapy in recurrent head and neck cancer. In addition to the high rate of complete remission, durability of clinical activity achieved a 67% overall survival and 42% progression free survival at one year.
- Reported the complete central nervous system clearance in a relapsed/refractory Waldenstrom’s macroglobulinemia patient, providing further validation for iopofosine I 131 to treat solid and hematologic tumors, including those located across the blood-

brain barrier.

- Enrolled the first patient in the company's Phase 1b clinical study of iopofosine I 131 in pediatric high-grade gliomas (pHGG). The study is supported by a \$2 million Fast Track SBIR grant from the National Institute of Health's National Cancer Institute (NCI), which was awarded based in part on the promising Phase 1a trial data.
- Announced promising preclinical data for its proprietary novel alpha-emitting phospholipid radiotherapeutic conjugate, CLR 121225 (^{225}Ac -CLR 121225) an actinium-labeled phospholipid ether (PLE), in pancreatic cancer models. The development of this compound expands the company's clinical pipeline of PLE cancer targeting compounds to include targeted alpha therapies (TATs).
- Announced strategic partnerships with leading community-based oncology networks Florida Cancer Specialists and American Oncology Network (AON) to advance the treatment of WM in the community setting.

First Quarter 2024 Financial Highlights

- **Cash and Cash Equivalents:** As of March 31, 2024, the company had cash and cash equivalents of \$40.0 million, compared to \$9.6 million as of December 31, 2023. Net cash used in operating activities during the three months ended March 31, 2024, was approximately \$13 million. The company believes its cash balance as of March 31, 2024, is adequate to fund its basic budgeted operations into the fourth quarter of 2024.
- **Research and Development Expense:** R&D expense for the three months ended March 31, 2024, was approximately \$7.4 million, compared to approximately \$6.7 million for the three months ended March 31, 2023. The overall increase in R&D expense was primarily a result of increased manufacturing and related costs related to the development of supply chain and production sourcing enhancements, partially offset by a decrease in general research and development costs.
- **General and Administrative Expense:** G&A expense for the three months ended March 31, 2024, was \$4.6 million, compared to \$2.1 million for the same period in 2023. The increase in G&A costs 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.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended March 31, 2024, was (\$21.6) million, or \$(0.74) per share, compared to \$(8.6) million, or \$(0.76) per share in the three months ended March 31, 2023.

Conference Call & Webcast Details

Cellectar management will host a conference call for investors today, May 14, 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 after the conclusion of the call.

About Celectar Biosciences, Inc.

Celectar 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.celestar.com and www.wmclinicaltrial.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.

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

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 40,031,181	\$ 9,564,988
Prepaid expenses and other current assets	1,337,184	888,225
Total current assets	41,368,365	10,453,213
Fixed assets, net	1,023,447	1,090,304
Right-of-use asset, net	486,847	502,283
Long-term assets	23,566	23,566
Other assets	6,214	6,214
TOTAL ASSETS	\$ 42,908,439	\$ 12,075,580
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 7,393,950	\$ 9,178,645
Warrant liability	8,800,000	3,700,000
Lease liability	73,994	58,979
Total current liabilities	16,267,944	12,937,624
Long-term lease liability, net of current portion	474,349	494,003
TOTAL LIABILITIES	16,742,293	13,431,627
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of March 31, 2024 and December 31, 2023	1,382,023	1,382,023
Series E-2 preferred stock, 1,225.00 shares authorized; 237.50 and 319.76 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	3,474,286	4,677,632
Series E-3 preferred stock, 2,205.00 shares authorized; 630.00 and 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	12,222,000	—
Common stock, \$0.00001 par value; 170,000,000 shares authorized; 33,164,466 and 20,744,110 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	332	207
Additional paid-in capital	248,151,681	210,066,630
Accumulated deficit	(239,064,176)	(217,482,539)
Total stockholders' equity	26,166,146	(1,356,047)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 42,908,439	\$ 12,075,580

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended March 31, 2024	2023
COSTS AND EXPENSES:		

Research and development	\$ 7,377,940	\$ 6,654,094
General and administrative	4,623,546	2,051,207
Total costs and expenses	<u>12,001,486</u>	<u>8,705,301</u>
LOSS FROM OPERATIONS	<u>(12,001,486)</u>	<u>(8,705,301)</u>
OTHER (LOSS) INCOME:		
Loss on valuation of warrants	(9,900,000)	—
Interest income, net	319,849	124,034
Total other (loss) income, net	<u>(9,580,151)</u>	<u>124,034</u>
NET LOSS	\$ (21,581,637)	\$ (8,581,267)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (0.74)	\$ (0.76)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	29,346,679	11,261,217

The accompanying notes are an integral part of these condensed consolidated financial statements.



Source: Cellestar Biosciences