

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): March 27, 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 March 27, 2024, we issued a press release announcing our financial results for the year ended December 31, 2023 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 March 27, 2024, titled "Collectar Biosciences Reports Financial Results for Year Ended 2023 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: March 27, 2024

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar Biosciences Reports Financial Results for Year Ended 2023 and Provides a Corporate Update

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

FLORHAM PARK, N.J., Mar. 27, 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 year ended December 31, 2023, and provided a corporate update.

“2023 was a year of significant progress for Collectar, culminating in the January announcement of the positive data from our pivotal study of iopofosine I 131 in Waldenstrom’s macroglobulinemia,” said James Caruso, president, and CEO of Collectar. “We continue to focus on the preparation of our NDA, which we plan to submit in the second half of 2024 and in parallel request accelerated approval, which if granted, would provide a six-month review period for the NDA. Our data in WM is truly impressive and we look forward to providing this meaningful new therapeutic for patients in a disease with limited treatment options.”

Fourth 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 that have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitors (BTKi). CLOVER WaM is the largest study to date in relapsed or refractory WM patients post-BTKi therapy and represents the most refractory population ever tested in clinical studies based upon a review of published literature. The CLOVER WaM study met its primary endpoint with a major response rate (MRR) of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]). The overall response rate (ORR) in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. Notably, iopofosine monotherapy achieved a 7.3% complete remission (CR) rate in this highly refractory WM population. A study data update is planned for Q2 of 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.
 - Announced that iopofosine I 131 demonstrated a pathological response with complete clonal clearance in a relapsed/refractory Waldenstrom’s macroglobulinemia (WM) patient with CNS involvement, also known as Bing-Neel Syndrome (BNS), enrolled in its Phase 2b CLOVER WaM pivotal trial.
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- Enrolled the first patient in the company’s Phase 1b clinical study of iopofosine I 131 in pediatric high-grade gliomas (pHGG). The open-label study will evaluate efficacy, safety, and tolerability assessing two dosing regimens to identify the optimal recommended dose and schedule of iopofosine I 131 in pHGG patients for a Phase 2 study. 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 121255 (^{255}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 physician-led, community-based oncology networks Florida Cancer Specialists and American Oncology Network (AON) to advance the treatment of WM in the community setting.
 - Announced a new licensing agreement with the Wisconsin Alumni Research Foundation (WARF) for intellectual property that was the result of collaborative research conducted at the University of Wisconsin-Madison (UW) with iopofosine I 131 in pediatric cancers. Under terms of the agreement, Collectar has an exclusive license to develop and commercialize iopofosine in various pediatric solid cancers, such as high-grade glioma, neuroblastoma, and sarcoma.
 - Expanded the Intellectual Property protection for its PDC Platform to deliver flavaglines as targeted anticancer payloads. The company received the Notice of Allowance for the patent entitled, “*Phospholipid-flavagline conjugates and methods of using the same for targeted cancer therapy*,” from the Japanese, Chinese, Eurasian, Brazilian, and Mexican patent authorities. These patent allowances in key global regions follow prior allowances for the same patent in the U.S., Europe, Australia, and Canada.
 - Announced the Tranche A warrants issued as part of the private placement announced in September 2023 were fully exercised. All participants in the previous financing, led by Rosalind Advisors, exercised their warrants with gross proceeds totaling approximately \$44.1 million.
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2023 Financial Highlights

- Cash and Cash Equivalents:** As of December 31, 2023, the company had cash and cash equivalents of \$9.6 million, compared to \$19.9 million as of December 31, 2022. The decrease in cash was primarily a result of research and development expenses, and general and administrative expenses. Net cash used in operating activities during the twelve months ended December 31, 2023, was approximately \$32.4 million. Net cash proceeds from the issuance of common stock, preferred stock, and warrants during 2023 was approximately \$22.9 million. We believe our cash balance as of December 31, 2023, in combination with the funds generated by the warrants exercised by investors in January 2024 is adequate to fund our basic budgeted operations into the fourth quarter of 2024.
- Research and Development Expense:** R&D expense for the year ended December 31, 2023, was approximately \$28.2 million, compared to approximately \$19.2 million for the year ended December 31, 2022. The overall increase in R&D expense was primarily a result of an increase in manufacturing and related costs related to greater production sourcing necessary to support clinical trials and establish commercial production capabilities.
- General and Administrative Expense:** G&A expense for the year ended December 31, 2023, was \$10.7 million, compared to \$9.6 million for the year ended December 31, 2022. The increase in G&A costs was primarily a result of an increase in personnel costs partially offset by a reduction in professional fees.
- Net Loss:** The net loss attributable to common stockholders for the year ended December 31, 2023, was \$(38.0) million, or \$(3.11) per share, compared to \$(28.6) million, or \$(4.05) per share in the year ended December 31, 2022.

Conference call & Webcast Details

Collectar management will host a conference call for investors today, March 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 1-888-886-7786 (in the U.S.) or 1-416-764-8658 (outside the U.S.). 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 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 September 30, 2023. 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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COLLECTAR BIOSCIENCES, INC. CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,564,988	\$ 19,866,358
Prepaid expenses and other current assets	888,225	663,243
Total current assets	10,453,213	20,529,601
Fixed assets, net	1,090,304	418,641
Right-of-use asset, net	502,283	560,334
Long-term assets	23,566	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 12,075,580	\$ 21,589,790
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 9,178,645	\$ 5,478,443
Warrant liability	3,700,000	—
Lease liability	58,979	50,847
Total current liabilities	12,937,624	5,529,290
Lease liability, net of current portion	494,003	552,981
TOTAL LIABILITIES	13,431,627	6,082,271
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' (DEFICIT) EQUITY :		
Series D preferred stock , 111.11 shares authorized; 111.11 shares issued and outstanding as of December 31, 2023 and 2022	1,382,023	1,382,023
Series E-2 preferred stock, 1,225.00 shares authorized; 319.76 and 0.00 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4,677,632	—

Common stock, \$0.00001 par value; 170,000,000 shares authorized; 20,744,110 and 9,385,272 shares issued and outstanding as of December 31, 2023 and 2022, respectively	207	94
Additional paid-in capital	210,066,630	193,624,445
Accumulated deficit	(217,482,539)	(179,499,043)
Total stockholders' (deficit) equity	(1,356,047)	15,507,519
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	<u>\$ 12,075,580</u>	<u>\$ 21,589,790</u>

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2023	2022
COSTS AND EXPENSES:		
Research and development	\$ 28,211,460	\$ 19,219,603
General and administrative	10,749,183	9,594,170
Total costs and expenses	<u>38,960,643</u>	<u>28,813,773</u>
LOSS FROM OPERATIONS	<u>(38,960,643)</u>	<u>(28,813,773)</u>
OTHER INCOME (EXPENSE):		
Warrant issuance expense	(470,000)	—
Gain on valuation of warrants	1,000,000	—
Interest income, net	387,147	152,519
Total other income, net	<u>917,147</u>	<u>152,519</u>
LOSS BEFORE INCOME TAXES	<u>(38,043,496)</u>	<u>(28,661,254)</u>
INCOME TAX BENEFIT	<u>(60,000)</u>	<u>(60,000)</u>
NET LOSS	<u>\$ (37,983,496)</u>	<u>\$ (28,601,254)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (3.11)</u>	<u>\$ (4.05)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>12,221,571</u>	<u>7,055,665</u>