

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 9, 2023

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 9, 2023, we issued a press release announcing our financial results for the year ended December 31, 2022 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 9, 2023, titled "Collectar Reports Financial Results for Year Ended 2022 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 9, 2023

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar Reports Financial Results for Year Ended 2022 and Provides a Corporate Update

FLORHAM PARK, N.J., Mar. 9, 2023 -- Collectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted treatments for cancer, today announced financial results for the year ended December 31, 2022 and provided a corporate update.

Fourth Quarter and Recent Corporate Highlights

- Presented preclinical data on the CLR 12120 series of targeted alpha therapies (TATs) at the 13th Annual World ADC Conference. The presentation, entitled: “Novel Conjugates – Radiotherapies,” given by Collectar’s Chief Operating Officer, Jarrod Longcor, highlighted data demonstrating the versatility of the phospholipid ether (PLE) targeting platform and the potential of the company’s alpha emitting precision medicines, supporting further development.
- Announced that Collectar, the Wisconsin Alumni Research Foundation, and Drs. Jamey Weichert and Anatoly Pinchuk have resolved a lawsuit filed by Collectar in October 2021 in the United States District Court for the Western District of Wisconsin concerning employee contracts and intellectual property rights in certain intellectual property pertaining to the diagnosis and treatment of cancer. The parties cannot further comment on that resolution, except to note that (i) all claims against Drs. Weichert and Pinchuk have been voluntarily dismissed, and (ii) Collectar has secured an irrevocable, non-exclusive license to the patents at issue in the lawsuit.
- Announced Shane Lea as chief commercial officer, overseeing all marketing and commercialization efforts for Collectar as it prepares for data from its pivotal trial in Waldenstrom’s macroglobulinemia.
- Appointed Dr. Andrei Shustov as senior vice president, medical to lead and provide oversight on all aspects of the Company’s clinical development program, medical affairs, and medical communications.
- Announced that a patient with primary central nervous system lymphoma enrolled in its Phase 2 CLOVER-1 Trial demonstrated a complete response according to the 2005 Response Criteria for CNS Lymphoma with total resolution of the tumor on imaging studies.

“2022 was highly productive for Collectar. We currently have 43 global sites actively recruiting patients for our pivotal study in Waldenstrom’s macroglobulinemia (WM). In parallel, our technology demonstrated consistently positive outcomes across multiple indications. At the American Society of Hematology Conference, we presented a 50% response rate achieved by iopofosine in post BCMA multiple myeloma patients and successfully concluded our phase 1a pediatric study and will initiate a phase 1b for High Grade Gliomas supported by a \$2 million NCI grant. We also reported the extraordinary complete response in a patient with relapsed/refractory CNS lymphoma further demonstrating iopofosine’s ability to cross the blood/brain barrier and target cancer,” said James Caruso, president and CEO of Collectar. “Importantly, we strengthened our commercial leadership with several key hires, including Shane Lea, who has launched six new hematology/oncology products, and Dr. Andrei Shustov, who provides a wealth of hematology/oncology clinical as well as study experience.”

Fourth Quarter 2022 Financial Highlights

- Cash and Cash Equivalents:** As of December 31, 2022, the company had cash and cash equivalents of \$19.9 million, compared to \$35.7 million as of December 31, 2021. Net cash used in operating activities during the year ended December 31, 2022 was approximately \$25.2 million. The company believes its cash on hand is adequate to fund budgeted operations into the fourth quarter of 2023.
- Research and Development Expense:** R&D expense for the year ended December 31, 2022 was approximately \$19.2 million, compared to approximately \$17.6 million for the year ended December 31, 2021. The overall increase in research and development expense was primarily a result of an increase in manufacturing and costs related to production sourcing and pre-clinical costs.
- General and Administrative Expense:** G&A expense for the year ended December 31, 2022 was \$9.5 million, compared to \$6.5 million for the same period in 2021. The increase in G&A costs was primarily a result of increased professional fees, a portion of which were non-recurring, as well as travel and personnel costs.
- Net Loss:** The net loss attributable to common stockholders for the year ended December 31, 2022 was (\$28.6) million, or (\$4.05) per share, compared to (\$24.1) million, or (\$4.35) per share, in the year ended December 31, 2021.

About Collectar Biosciences, Inc.

Collectar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs 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 PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. The company’s PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company’s product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, open-label, pivotal expansion cohort in relapsed or refractory WM patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin’s lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

The company has established exclusivity on a broad U.S. and international intellectual property rights portfolio around its proprietary cancer-targeting PLE technology platform, including iopofosine and its PDC programs.

In addition to the company's exclusivity to iopofosine and its phospholipid ethers conjugated to small molecules, peptides, and oligos, the company now has non-exclusive rights to the use of the phospholipid ether platform when conjugating with a chelator to bind select metal radioisotopes.

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 of the impact of the COVID-19 pandemic. 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, 2022. 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

Investors:

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+++ TABLES TO FOLLOW +++

COLLECTAR BIOSCIENCES, INC. CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 19,866,358	\$ 35,703,975
Prepaid expenses and other current assets	663,243	867,485
Total current assets	20,529,601	36,571,460
Fixed assets, net	418,641	344,491
Right-of-use asset, net	560,334	204,644
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 21,589,790	\$ 37,201,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 5,478,443	\$ 3,854,914
Lease liability	50,847	135,449
Total current liabilities	5,529,290	3,990,363
Lease liability, net of current portion	552,981	166,292
TOTAL LIABILITIES	6,082,271	4,156,655
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Series D preferred stock: 111 shares issued and outstanding as of December 31, 2022 and 2021, respectively	1,382,023	1,382,023
Common stock, \$0.00001 par value; 160,000,000 shares authorized; 9,385,272 and 6,110,125 shares issued and outstanding as of December 31, 2022 and 2021, respectively	94	61
Additional paid-in capital	193,624,445	182,560,859
Accumulated deficit	(179,499,043)	(150,897,789)
Total stockholders' equity	15,507,519	33,045,154
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 21,589,790	\$ 37,201,809

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2022	2021
COSTS AND EXPENSES:		
Research and development	\$ 19,219,603	\$ 17,586,469
General and administrative	9,594,170	6,544,811
Total costs and expenses	28,813,773	24,131,280
LOSS FROM OPERATIONS	(28,813,773)	(24,131,280)
OTHER INCOME:		
Other income	—	6,634
Interest income, net	152,519	2,284
Total other income, net	152,519	8,918
LOSS BEFORE INCOME TAXES	(28,661,254)	(24,122,362)
INCOME TAX BENEFIT	(60,000)	—
NET LOSS	\$ (28,601,254)	\$ (24,122,362)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (4.05)	\$ (4.35)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	7,055,665	5,551,572