

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): August 14, 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 August 14, 2023, we issued a press release announcing our financial results for the three and six months ended June 30, 2023. 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 August 14, 2023, entitled “Collectar Reports Financial Results for Second Quarter 2023 and Provides a Corporate Update”](#)

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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: August 14, 2023

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar Reports Financial Results for Second Quarter 2023 and Provides a Corporate Update

FLORHAM PARK, N.J., August 14, 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 second quarter ended June 30, 2023 and provided a corporate update.

Second Quarter and Recent Corporate Highlights

- In June, the company provided an update for its iopofosine I 131 clinical program and guidance related to its Waldenstrom's macroglobulinemia (WM) CLOVER-WaM pivotal trial, as well as preclinical advancements to its proprietary phospholipid ether drug conjugate platform. The updates included:
 - o Top-line data from its WM CLOVER-WaM pivotal trial is expected in 2H23 and assuming NDA approval, the company remains on target for a 2024 product launch.
 - o The company plans to initiate its Phase 1b study in pediatric high-grade gliomas (pHGG) in the third quarter of 2023.
 - o The central nervous system lymphoma (CNSL) cohort from its Phase 2a trial expanded to further evaluate iopofosine I 131 in this indication. The company previously reported a complete response in a CNSL patient
 - o The company's COO, Jarrod Longcor, delivered an oral presentation of iopofosine I 131 for the treatment of multiple myeloma at the Society of Nuclear Medicine and Molecular Imaging Annual Conference. Iopofosine I 131 has been evaluated in over 125 multiple myeloma patients with response rates ranging from 40% to 62% in triple class refractory, quad/penta refractory, post-BCMA and high-risk patients.
 - o The company presented updates on its phospholipid ether cancer targeting platform at several conferences, including SNMMI, Targeted Radiotherapy Conference, Oncology 2023, and Therapeutic Area Partnership Oncology. The presentations highlighted the platform's broad utility to provide targeted intracellular delivery of multiple cancer treatment modalities.

"We look forward to reporting top-line data from our WM pivotal trial in the second half of this year. We believe the novel method of action and product profile for iopofosine I 131 is clearly differentiated and can address patients' needs in relapsed or refractory WM with the potential to establish a new standard of care. Our commercialization efforts will strategically take advantage of the highly scalable and concentrated WM market to drive early use and adoption," said James Caruso, president and CEO of Collectar. "We also continue to develop iopofosine I 131 across multiple indications, including CNSL and pHGG's as well as multiple myeloma, and are looking forward to a transformational second half of 2023."

Second Quarter 2023 Financial Highlights

- **Cash and Cash Equivalents:** As of June 30, 2023, the company had cash and cash equivalents of \$5.2 million, compared to \$19.9 million as of December 31, 2022. Net cash used in operating activities during the three months ended June 30, 2023 was approximately \$7.5 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 three months ended June 30, 2023 was approximately \$6.3 million, compared to approximately \$4.5 million for the three months ended June 30, 2022. The overall increase in research and development expense was primarily a result of increased manufacturing costs, production sourcing, and general research and development costs due to an increase in personnel, slightly offset by a reduction in clinical project cost and pre-clinical project costs.
- **General and Administrative Expense:** G&A expense for the three months ended June 30, 2023 was \$2.0 million, compared to \$2.9 million for the same period in 2022. The overall decrease in G&A costs was primarily driven by a decrease in professional fees and personnel costs.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended June 30, 2023 was (\$8.2) million, or (\$0.73) per share, compared to (\$7.4) million, or (\$1.22) per share, for the three months ended June 30, 2022.

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 +++

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

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 5,152,972	\$ 19,866,358
Prepaid expenses and other current assets	456,679	663,243
Total current assets	5,609,651	20,529,601
Fixed assets, net	337,434	418,641
Right-of-use asset, net	532,300	560,334
Long-term assets	23,566	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 6,509,165	\$ 21,589,790
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 6,391,673	\$ 5,478,443
Lease liability	53,640	50,847
Total current liabilities	6,445,313	5,529,290
Long-term lease liability, net of current portion	530,856	552,981
TOTAL LIABILITIES	6,976,169	6,082,271
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' (DEFICIT) EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series D preferred stock: 111 issued and outstanding as of June 30, 2023 and December 31, 2022	1,382,023	1,382,023
Common stock, \$0.00001 par value; 160,000,000 shares authorized; 9,740,507 and 9,385,272 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	97	94
Additional paid-in capital	194,452,408	193,624,445
Accumulated deficit	(196,301,532)	(179,499,043)
Total stockholders' (deficit) equity	(467,004)	15,507,519
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	\$ 6,509,165	\$ 21,589,790

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
COSTS AND EXPENSES:				
Research and development	\$ 6,308,430	\$ 4,498,657	\$ 12,962,524	\$ 8,385,656
General and administrative	1,985,572	2,936,867	4,036,779	5,190,095
Total costs and expenses	8,294,002	7,435,524	16,999,303	13,575,751

LOSS FROM OPERATIONS	(8,294,002)	(7,435,524)	(16,999,303)	(13,575,751)
OTHER INCOME:				
Interest income, net	72,780	481	196,814	911
Total other income	72,780	481	196,814	911
NET LOSS	<u>\$ (8,221,222)</u>	<u>\$ (7,435,043)</u>	<u>\$ (16,802,489)</u>	<u>\$ (13,574,840)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.73)</u>	<u>\$ (1.22)</u>	<u>\$ (1.49)</u>	<u>\$ (2.22)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>11,261,217</u>	<u>6,110,124</u>	<u>11,261,217</u>	<u>6,110,125</u>