
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): November 3, 2022

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 November 3, 2022, we issued a press release announcing our financial results for the three months and nine months ended September 30, 2022. 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
<u>99.1</u>	<u>Press release dated November 3, 2022, entitled “Collectar Reports Financial Results for Third Quarter 2022 and Provides a Corporate Update”</u>
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: November 3, 2022

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

Title: Chief Financial Officer

Collectar Reports Financial Results for Third Quarter 2022 and Provides a Corporate Update

FLORHAM PARK, N.J., November 3, 2022 -- 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 third quarter ended September 30, 2022 and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- In October, the company closed concurrent registered direct and private placement offerings totaling \$10.7 million in gross proceeds with institutional investors including the company's top three stockholders. The company sold 3,275,153 shares of the company's common stock at \$2.085 per share in the registered direct offering, while warrants to purchase up to an aggregate of 3,275,153 shares of common stock were sold in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement offering, the company sold institutional investors pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and warrants to purchase an aggregate of 1,875,945 shares of common stock. The company intends to use the net proceeds from the registered direct offering and the private placements for funding clinical studies, research and development, working capital and general corporate purposes.
 - Announced publication of data from the company's expansion cohort of the Phase 2 CLOVER-1 Study of iopofosine in relapsed/refractory multiple myeloma in the September issue of Blood Cancer Journal, a peer-reviewed Nature journal. The paper, entitled "*Iopofosine I-131 treatment in late-line patients with relapsed/refractory multiple myeloma post anti-BCMA immunotherapy*," Initial patient data showed an overall response rate (ORR) of 50% in quad-class refractory multiple myeloma who have failed anti-BCMA Immunotherapy with a median of nine lines of therapy. The mean overall survival at the time of data cutoff was 9.1 months, with median overall survival not yet reached.
 - Awarded \$2 million grant to expand its ongoing Phase 1 study of iopofosine I 131 in pediatric brain tumors. The grant was awarded by the National Institute of Health's National Cancer Institute (NCI) based upon initial signals of efficacy. The funding allows for an expansion from the Part 1a to the Part 1b portion of the company's ongoing Phase 1 pediatric study. The ongoing Phase 1a is designed to determine the safety, tolerability, and initial efficacy of iopofosine in pediatric brain tumors whereas the Phase 1b is designed to identify the dose and dosing regimen that results in optimal efficacy. Previously announced preliminary data demonstrated therapeutic responses to iopofosine as evidenced by changes in multiple tumor parameters and patients experiencing extended progression free survival.
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“Iopofosine continues to demonstrate its potential as a novel targeted radiotherapeutic in multiple ongoing trials in Waldenström’s macroglobulinemia (WM), multiple myeloma, CNS lymphoma, pediatric brain tumors and sarcomas. Additionally, we appreciate the recognition and additional grant from the NCI to support the expansion of our pediatric brain tumor trial into a Phase 1b based on demonstrated safety and activity,” said James Caruso, president and CEO of Collectar. “Our third quarter cash balance of \$17.8 million, combined with the net proceeds from our successful October financing, provide the necessary capital to achieve several key milestones. We look forward to sharing topline data from our pivotal Phase 2b WM trial in the first half of 2023, and anticipate providing additional data from our phase 2a trial and our phase 1 pediatric trial in the near term.”

Third Quarter 2022 Financial Highlights

- **Cash and Cash Equivalents:** As of September 30, 2022, the company had cash and cash equivalents of \$17.8 million, compared to \$35.7 million as of December 31, 2021. Net cash used in operating activities during the nine months ended September 30, 2022 was approximately \$17.8 million. Subsequent to the end of the quarter, the Company raised \$10.7 million in gross proceeds through a combined registered direct and PIPE offering. The company believes its cash on hand, inclusive of the October raise, is adequate to fund planned budgeted operations into the fourth quarter of 2023.
- **Research and Development Expense:** R&D expense for the three months ended September 30, 2022 was approximately \$5.4 million, compared to approximately \$3.9 million for the three months ended September 30, 2021. For the nine months ended September 30, 2022, R&D expense was approximately \$13.8 million, while the comparable period in 2021 was \$13.2 million. The increase for both the three- and nine-month periods was primarily a result of the timing of activities related to our ongoing WM pivotal trial.
- **General and Administrative Expense:** G&A expense for the three months ended September 30, 2022 was \$2.4 million, compared to \$1.9 million for the same period in 2021. G&A expense in the nine months ended September 30, 2022 was approximately \$7.6 million, as compared to approximately \$5.0 million in the prior year. These increases were driven largely by professional fees and personnel costs.
- **Net Loss:** The net loss attributable to common stockholders for the quarter ended September 30, 2022 was (\$7.8) million, or (\$1.28) per share, compared to (\$5.8) million, or (\$0.97) per share, in the quarter ended September 30, 2021, while the loss attributable to common stockholders for the nine months ended September 30, 2022 was (\$21.4) million, or (\$3.50) per share, compared to (\$18.2) million, or (\$3.39) per share, in 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.

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, 2021, and our Form 10-Q for the quarter ended September 30, 2022, when filed. 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)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 17,785,322	\$ 35,703,975
Prepaid expenses and other current assets	975,936	867,485
Total current assets	18,761,258	36,571,460
Fixed assets, net	338,944	344,491
Right-of-use asset, net	138,097	204,644
Long-term and other assets	81,214	81,214
TOTAL ASSETS	\$ 19,319,513	\$ 37,201,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 6,367,035	\$ 3,854,914
Lease liability	148,200	135,449
Total current liabilities	6,515,235	3,990,363
Long-term lease liability, net of current portion	53,769	166,292
TOTAL LIABILITIES	6,569,004	4,156,655
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series D preferred stock: 111 shares issued and outstanding	1,382,023	1,382,023
Common stock, \$0.00001 par value; 160,000,000 shares authorized; 6,110,119 and 6,110,125 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	61	61
Additional paid-in capital	183,652,376	182,560,859
Accumulated deficit	(172,283,951)	(150,897,789)
Total stockholders' equity	12,750,509	33,045,154
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 19,319,513	\$ 37,201,809

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
COSTS AND EXPENSES:				
Research and development	\$ 5,380,190	\$ 3,937,464	\$ 13,765,846	\$ 13,198,294
General and administrative	2,435,296	1,882,190	7,625,391	5,009,581
Total costs and expenses	<u>7,815,486</u>	<u>5,819,654</u>	<u>21,391,237</u>	<u>18,207,875</u>
LOSS FROM OPERATIONS	<u>(7,815,486)</u>	<u>(5,819,654)</u>	<u>(21,391,237)</u>	<u>(18,207,875)</u>
OTHER INCOME:				
Interest income, net	4,164	590	5,075	3,611
Total other income	<u>4,164</u>	<u>590</u>	<u>5,075</u>	<u>3,611</u>
NET LOSS	<u>\$ (7,811,322)</u>	<u>\$ (5,819,064)</u>	<u>\$ (21,386,162)</u>	<u>\$ (18,204,264)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (1.28)</u>	<u>\$ (0.97)</u>	<u>\$ (3.50)</u>	<u>\$ (3.39)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>6,110,119</u>	<u>5,986,837</u>	<u>6,110,123</u>	<u>5,363,342</u>