

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 8, 2021**

CELLECTAR 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

(I.R.S. Employer
Identification No.)

100 Campus Drive, Florham Park, New Jersey 07932

(Address of principal executive offices, and zip code)

(608) 441-8120

(Registrant's telephone number, including area code)

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	CLRB	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 8, 2021, we issued a press release announcing our financial results for the third quarter ended September 30, 2021 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 November 8, 2021, titled "Cellectar Reports Financial Results for the Third Quarter 2021 and Provides a Corporate Update"
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

SIGNATURE

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.

Dated: November 8, 2021

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Collectar Reports Financial Results for the Third Quarter 2021 and Provides a Corporate Update

FLORHAM PARK, N.J., November 8, 2021 -- Collectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of targeted drugs for the treatment of cancer, today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- Announced the completion of the Part A portion of a safety and tolerability study of iopofosine I-131 (iopofosine) in combination with external beam radiation (EBRT) in relapsed or refractory head and neck cancer. The investigator-initiated study is being conducted by the University of Wisconsin as part of a Specialized Program of Research Excellence (SPORE) grant awarded by the National Cancer Institute (NCI).
 - o The study objective is to determine if combining iopofosine with EBRT can reduce the amount or fractions (doses) of EBRT required, which has the potential to diminish the number and severity of EBRT associated adverse events.
 - o Preliminary data suggest that iopofosine is safe and tolerated in combination with EBRT for relapsed or refractory head and neck cancer.
- Awarded a peer-reviewed National Institutes of Health (NIH) Phase II Small Business Innovation Research (SBIR) grant of approximately \$2 Million from the NCI. The grant will support the ongoing global pivotal study and clinical development of iopofosine in Waldenstrom's macroglobulinemia (WM).
- Announced collaboration with BBK Worldwide to provide new concierge services for patients participating in Collectar's clinical studies. These services are designed to improve patient's and their caregiver's access to high quality care and innovative treatments for their cancer.
- Announced commercial manufacturing and supply agreement with Evergreen Theragnostics, a global radiopharmaceutical contract development and manufacturing organization (CDMO), to provide long term commercial supply of iopofosine and clinical study material for the company's pivotal study in WM, as well as for the ongoing Phase 1 and Phase 2 clinical studies.

"We remain highly focused on driving our pivotal study of iopofosine in Waldenstrom's and in parallel advancing the ongoing Phase 2b clinical study for late line, hexa-drug refractory multiple myeloma patients along with our two Phase 1 studies in pediatric and head and neck cancers" said James Caruso, president and CEO of Collectar. "Our collaboration with Evergreen Theragnostics expands our manufacturing capabilities to help reduce the risks inherent in single sourcing of drug supply and provides the capability to scale supply for future studies and potential commercialization. The recent deal with BBK Worldwide will allow us to more efficiently serve our patients and remove barriers to study participation as we continue to develop iopofosine in WM and other oncology indications. With \$40.3 million in cash and cash equivalents as of September 30, we are supported by a strong balance sheet that will fund our expected clinical and regulatory milestones into the second half of 2023."

Third Quarter Financial Highlights

- **Cash and Cash Equivalents:** As of September 30, 2021, the company had cash and cash equivalents of \$40.3 million compared to \$57.2 million at December 31, 2020. Cash used in operating activities was approximately \$18.1 million during the nine months ended September 30, 2021 as compared to \$10.1 million during the nine months ended September 30, 2020.
- **Research and Development Expense:** R&D expense for the three months ended September 30, 2021 was \$3.9 million, compared to \$2.7 million for the three months ended September 30, 2020. The cumulative R&D spending for the first nine months of 2021 was \$13.2 million as compared to \$7.8 million for the first nine months of 2020. The increase in R&D expense year-to-date in 2021 was primarily a result of start-up costs for our WM pivotal study, clinical project costs and general research and development costs offset by a decrease in manufacturing and related costs.
- **General and Administrative Expense:** G&A expense for the three months ended September 30, 2021 was \$1.9 million compared to \$1.2 million for the three months ended September 30, 2020. The cumulative G&A spending for the first nine months of 2021 were \$5.0 million as compared to \$3.7 million for the first nine months of 2020. The increase in G&A expense year-to-date in 2021 was primarily a result of an increase in professional fees and insurance, personnel costs and stock-based compensation expense.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended September 30, 2021 was (\$5.8) million, or (\$0.10) per share, compared to (\$3.9) million, or (\$0.15) per share, in 2020. Net loss attributable to common stockholders for the nine months ended September 30, 2021 was (\$18.2) million, or (\$0.34) per share, compared to (\$11.5) million, or (\$0.69) per share, in 2020.

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, delivering 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), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, 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.

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, 2020 and our Form 10-Q for the quarter ended September 30, 2021, 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:**

Monique Kosse
 Managing Director
 LifeSci Advisors
 212-915-3820
monique@lifesciadvisors.com

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 40,344,727	\$ 57,165,377
Prepaid expenses and other current assets	1,048,082	774,432
Total current assets	41,392,809	57,939,809
Fixed assets, net	254,041	355,982
Right-of-use asset, net	225,205	282,365
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 41,953,269	\$ 58,659,370
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,034,489	\$ 3,443,197
Lease liability	131,406	119,904
Total current liabilities	3,165,895	3,563,101
Long-term lease liability	201,970	301,740
TOTAL LIABILITIES	3,367,865	3,864,841
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series C preferred stock: 0 and 215 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	1,148,204
Series D preferred stock: 111 and 1,519 issued and outstanding as of September 30, 2021 and December 31, 2020 respectively	1,382,023	18,887,645
Common stock, \$0.00001 par value; 160,000,000 and 80,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 61,101,264 and 45,442,729 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	611	454
Additional paid-in capital	182,182,461	161,533,653
Accumulated deficit	(144,979,691)	(126,775,427)
Total stockholders' equity	38,585,404	54,794,529
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 41,953,269	\$ 58,659,370

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
COSTS AND EXPENSES:				
Research and development	\$ 3,937,464	\$ 2,683,944	\$ 13,198,294	\$ 7,765,673
General and administrative	1,882,190	1,225,993	5,009,581	3,725,153
	5,819,654	3,909,937	18,207,875	11,490,826
Total costs and expenses	5,819,654	3,909,937	18,207,875	11,490,826
LOSS FROM OPERATIONS	(5,819,654)	(3,909,937)	(18,207,875)	(11,490,826)

OTHER INCOME:				
Interest income, net	<u>590</u>	<u>374</u>	<u>3,611</u>	<u>11,730</u>
Total other income	<u>590</u>	<u>374</u>	<u>3,611</u>	<u>11,730</u>
NET LOSS	<u>\$ (5,819,064)</u>	<u>\$ (3,909,563)</u>	<u>\$ (18,204,264)</u>	<u>\$ (11,479,096)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.10)</u>	<u>\$ (0.15)</u>	<u>\$ (0.34)</u>	<u>\$ (0.69)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>59,868,374</u>	<u>26,326,782</u>	<u>53,633,421</u>	<u>16,539,183</u>