

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 10, 2020**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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. ☐

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
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On August 10, 2020, we issued a press release announcing our results for the three months ended June 30, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
<u>99.1</u>	<u>Press release dated August 10, 2020, titled "Collectar Reports Second Quarter 2020 Financial Results and Provides a Corporate Update"</u>

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: August 10, 2020

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Cellecstar Reports Second Quarter 2020 Financial Results and Provides a Corporate Update

FLORHAM PARK, N.J., August 10, 2020 -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced financial results for the second quarter ended June 30, 2020 and provided a corporate update.

Second Quarter and Recent Corporate Highlights

- Received Fast Track Designation for CLR 131 in lymphoplasmacytic lymphoma (LPL)/ Waldenstrom's macroglobulinemia (WM) from the U.S. Food and Drug Administration (FDA);
- Received Small and Medium-Sized Enterprise (SME) status from the European Medicines Agency's (EMA) Micro, Small and Medium-sized Enterprise office. SME status allows Cellecstar to participate in significant financial incentives and be eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data;
- Expanded IP coverage in Europe with the receipt of two composition of matter and use patents. The first patent expands protection for the company's proprietary PLE targeted delivery vehicle analogs in combination with a broad range of chemotherapeutics such as paclitaxel, gemcitabine, and other classes of small molecule chemotherapeutic agents. The second patent covers the treatment and/or diagnosis of cancer and cancer stem cells with CLR 131;
- Strengthened the management team with the appointment of Dr. John Friend, chief medical officer; and
- Completed an underwritten public offering for gross proceeds of \$20 million

"We continue to enroll relapsed/refractory multiple myeloma and LPL/WM patients in the Phase 2b portion of our ongoing CLOVER-1 study and prepare for the initiation of our pivotal study expected in Q4 of 2020 while advancing our Phase 1 pediatric study," said James Caruso, president and CEO of Cellecstar. "We also successfully executed on other key fronts. The FDA granted CLR 131 Fast Track Designation in LPL/WM; we expanded our IP portfolio with two new European patents and significantly strengthened our balance sheet with the recent financing."

Second Quarter 2020 Financial Highlights

- **Cash and Cash Equivalents:** As of June 30, 2020, the company had cash and cash equivalents of \$22.5 million compared to \$10.6 million at December 31, 2019. Cash used in operating activities was approximately \$6.6 million during the six months ended June 30, 2020 as compared to \$5.5 million during the six months ended June 30, 2019.
- **Research and Development Expense:** R&D expense for the three months ended June 30, 2020 was \$2.5 million, compared to \$1.8 million for the three months ended June 30, 2019. The cumulative R&D spending for the first six months of 2020 was \$5.1 million as compared to \$4.1 million for the first six months of 2019. The increase in R&D expense year-to-date in 2020 was primarily a result of general R&D cost from personnel related expenses and clinical project costs. Manufacturing and related costs decreased and the costs of preclinical studies were relatively consistent.
- **General and Administrative Expense:** G&A expense for the three months ended June 30, 2020 was \$1.2 million compared to \$1.4 million for the three months ended June 30, 2019. The cumulative G&A spending for the first six months of 2020 were of \$2.5 million as compared to \$2.7 million for the first six months of 2019. The decrease in G&A expense year-to-date in 2020 was primarily a result of lower stock-based compensation expense.
- **Net Loss:** The net loss attributable to common stockholders for the three months ended June 30, 2020 was (\$3.6) million, or (\$0.26) per share, compared to (\$3.2) million, or (\$0.46) per share, in 2019. Net loss attributable to common stockholders for the six months ended June 30, 2020 was (\$7.6) million, or (\$0.65) per share, compared to (\$6.8) million, or (\$1.15) per share, in 2019.

About Collectar Biosciences, Inc.

Collectar Biosciences is focused on the discovery, development and commercialization 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 lead PDC therapeutic, CLR 131, is currently in two clinical studies. The CLOVER-1 Phase 2 study completed the Part A dose-exploration portion, conducted in relapsed/refractory (r/r) B-cell malignancies, and is now enrolling in the Part B expansion cohorts evaluating a two cycle dosing regimen that provides approximately 100mCi total body dose of CLR 131 in relapsed/refractory (r/r) multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenström's macroglobulinemia (LPL/WM). The data from the Part A portion was announced on February 19, 2020.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 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 7 leading pediatric cancer centers.

The company's product pipeline includes one preclinical PDC chemotherapeutic program (CLR 1900) and multiple partnered PDC assets.

For more information, please visit www.collectar.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 recent 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 CLR 131, 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 CLR 131, 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, 2019, our Form 10-Q for the quarter ended March 31, 2020 and our Form 10-Q for the quarter ended June 30, 2020, 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. 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, LLC
646-915-3820
monique@lifesciadvisors.com

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 22,450,203	\$ 10,614,722
Prepaid expenses and other current assets	593,590	770,951
Total current assets	23,043,793	11,385,673
Fixed assets, net	410,624	435,083
Right-of-use asset, net	316,917	348,841
Long-term assets	81,214	75,000
Other assets	—	6,214
TOTAL ASSETS	<u>\$ 23,852,548</u>	<u>\$ 12,250,811</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,207,041	\$ 2,663,873
Lease liability	112,713	105,885
Total current liabilities	3,319,754	2,769,758
LONG-TERM LIABILITIES:		
Lease liability	363,534	421,644
Loan payable	184,000	—
Total long-term liabilities	547,534	421,644
TOTAL LIABILITIES	<u>3,867,288</u>	<u>3,191,402</u>
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series C preferred stock: 215 issued and outstanding as of June 30, 2020 and December 31, 2019	1,148,204	1,148,204
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 25,472,383 and 9,386,689 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	254	94
Additional paid-in capital	138,087,590	119,592,366
Accumulated deficit	(119,250,788)	(111,681,255)
Total stockholders' equity	19,985,260	9,059,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 23,852,548</u>	<u>\$ 12,250,811</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
COSTS AND EXPENSES:				
Research and development	\$ 2,465,392	\$ 1,809,547	\$ 5,081,729	\$ 4,117,944
General and administrative	1,156,842	1,390,812	2,499,160	2,712,227
Total costs and expenses	<u>3,622,234</u>	<u>3,200,359</u>	<u>7,580,889</u>	<u>6,830,171</u>
LOSS FROM OPERATIONS	<u>(3,622,234)</u>	<u>(3,200,359)</u>	<u>(7,580,889)</u>	<u>(6,830,171)</u>
OTHER INCOME:				
Gain/(Loss) on revaluation of derivative warrants	—	1,000	—	(3,000)
Interest income, net	10,309	11,798	11,356	23,969
Total other income	<u>10,309</u>	<u>12,798</u>	<u>11,356</u>	<u>20,969</u>
NET LOSS	<u>\$ (3,611,925)</u>	<u>\$ (3,187,561)</u>	<u>\$ (7,569,533)</u>	<u>\$ (6,809,202)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.26)</u>	<u>\$ (0.46)</u>	<u>\$ (0.65)</u>	<u>\$ (1.15)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>13,793,548</u>	<u>6,963,301</u>	<u>11,591,605</u>	<u>5,935,111</u>