

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 12, 2019**

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))

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 August 20, 2019	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	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 (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. ☐

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On August 12, 2019, we issued a press release announcing our results for the three and six months ended June 30, 2019. 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 12, 2019, titled "Collectar Reports Second Quarter 2019 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 12, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Charles T. Bernhardt

Name: Charles T. Bernhardt

Title: Interim Chief Financial Officer



Collectar Reports Second Quarter 2019 Financial Results and Provides a Corporate Update

FLORHAM PARK, N.J., August 12, 2019 -- Collectar 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, 2019, and provided a corporate update.

"We made considerable progress on both the clinical and regulatory fronts during the second quarter and subsequent period. CLR 131 continues to advance, delivering encouraging preliminary data with improving efficacy and a clear dose response in our ongoing Phase 1 study. In addition, the company received FDA Fast Track Designation for CLR 131 in two separate indications and believe that we continue to track toward a registrational study in at least one B-cell hematologic malignancy from our ongoing Phase 2 CLOVER-1 study," said Jim Caruso, CEO of Collectar. "Our recently adopted fractionated dosing schedule of CLR 131 has led to the improved efficacy and tolerability observed in our latest cohorts and we are moving forward with this dosing strategy in our recently initiated pediatric Phase 1 trial for the treatment of life-threatening cancers."

Second Quarter and Recent Corporate Highlights

- Announced initial results from Cohort 6 in the company's ongoing Phase 1 clinical study with CLR 131 in Relapsed or Refractory Multiple Myeloma (R/R MM). Data from Cohort 6 showed improved efficacy and a clear dose response compared to prior cohorts, including a 50% overall response rate, a 50% minimal response rate and 100% disease control rate. The International Myeloma Working Group defines a partial response as a 50% to 89.9% reduction in the marker of disease and minimal response as 25% to 49.9% reduction in the marker of disease. One patient achieved a minimal response with a 48% reduction in their m-protein. The other patient achieving a minimal response had a 39% reduction in m-protein remains on study and continues to be evaluated.
 - Expanded the third cohort of our ongoing Phase 2 CLOVER-1 study of CLR 131 after preliminary results showed it exceeded pre-specified performance criteria. We are currently enrolling patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL) and marginal zone lymphoma (MZL) in the third cohort. The company continues to expect to report top-line data from the Phase 2 CLOVER-1 study in 2019.
 - Received FDA Fast Track Designation for CLR 131 in two separate indications: in fourth line or later relapsed/refractory multiple myeloma and in relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL). CLR 131 is currently being evaluated in Collectar's ongoing CLOVER-1 Phase 2 clinical study in patients with select B-Cell lymphomas, including multiple myeloma and DLBCL.
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Closed on a financing for gross proceeds of \$10 million. In a registered direct offering, Collectar issued 1,982,000 shares of common stock. In a separate concurrent private placement transaction, Collectar sold 2,018,000 shares of common stock. In conjunction with the offerings, the company also issued 4,000,000 warrants to purchase common stock in the private placement.

Second Quarter Summary of Financial Results

Cash and Cash Equivalents: As of June 30, 2019, cash and cash equivalents were approximately \$16.8 million compared to \$13.3 million as of December 31, 2018. We believe that our cash balance is adequate to fund our basic budgeted operations through the fourth quarter of 2020. Cash used in operating activities was approximately \$5.5 million during the six months ended June 30, 2019 as compared to \$5.7 million used during the six months ended June 30, 2018.

Research and Development Expense: R&D expense for the three months ended June 30, 2019 was \$1.8 million compared to \$1.7 million in the three months ended June 30, 2018. The cumulative R&D spending for the first six months of 2019 was \$4.1 million as compared to \$3.8 million for the first six months of 2018. The majority of the company's R&D spend for year-to-date 2019 was dedicated to the start-up and support of our pediatric study with \$1.3 million and \$2.9 million spent for the three and six months ending June 30, 2019, respectively, related to clinical project costs and manufacturing expenses.

General and Administrative Expense: General and administrative (G&A) expense for the three months ended June 30, 2019 was approximately \$1.4 million compared to approximately \$1.2 million in the three months ended June 30, 2018. The cumulative G&A spending for the first six months of 2019 were of \$2.7 million as compared to \$2.6 million for the first six months of 2018.

Net Loss: Net loss for the three months ended June 30, 2019 was \$(3.2) million, or a loss of \$(0.46) per diluted share, compared to a net loss of \$(2.9) million, or a loss of \$(1.69) per diluted share, in the three months ended June 30, 2018. Net loss for the six months ended June 30, 2019 was \$(6.8) million, or a loss of \$(1.15) per diluted share, compared to a net loss of \$(6.4) million, or a loss of \$(3.75) per diluted share, in the six months ended June 30, 2018.

About CLR 131

CLR 131 is a small-molecule, targeted Phospholipid Drug Conjugate™ (PDC) designed to deliver cytotoxic radiation directly to cancer cells, while limiting exposure to healthy cells. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-Cell lymphomas, and two Phase 1 dose-escalating clinical studies, one in multiple myeloma and one in pediatric solid tumors and lymphoma. CLR 131 was granted Orphan Drug designation for the treatment of multiple myeloma, and was granted Orphan Drug and Rare Pediatric Disease designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

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 (R&D) collaborations. The company's core objective is to leverage its proprietary 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. Our PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and we plan to develop PDCs independently and through research and development collaborations.

The company's lead PDC therapeutic, CLR 131, is currently in three clinical studies – a Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in refractory/relapsing (R/R) B-Cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-Cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with R/R multiple myeloma (MM) and a Phase 1 study in pediatric solid tumors and lymphoma.

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

For more information, please visit www.collectar.com.

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. 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, the completion of clinical trials, the FDA review process and other government regulation, 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, 2018 and Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019. 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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CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 16,849,631	\$ 13,255,616
Restricted cash	—	55,000
Prepaid expenses and other current assets	1,333,846	641,218
Total current assets	18,183,477	13,951,834
Fixed assets, net	492,716	543,339
Right-of-use asset, net	378,280	—
Long-term assets	75,000	540,823
Other assets	6,214	18,086
TOTAL ASSETS	\$ 19,135,687	\$ 15,054,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,528,017	\$ 1,543,819
Derivative liability	46,000	43,000
Capital lease obligations, current portion	568	2,213
Deferred rent	—	33,090
Lease liability	99,402	—
Total current liabilities	2,673,987	1,622,122
LONG-TERM LIABILITIES:		
Deferred rent, less current portion	—	170,999
Lease liability	476,247	—
Total long-term liabilities	476,247	170,999
TOTAL LIABILITIES	3,150,234	1,793,121
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Series C preferred stock: 215 and 473 issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1,148,204	2,526,049
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 9,386,703 and 4,732,387 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	94	47
Additional paid-in capital	119,234,700	108,323,208
Accumulated deficit	(104,397,545)	(97,588,343)
Total stockholders' equity	15,985,453	13,260,961
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 19,135,687	\$ 15,054,082

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
COSTS AND EXPENSES:				
Research and development	\$ 1,809,547	\$ 1,723,087	\$ 4,117,944	\$ 3,802,955
General and administrative	1,390,812	1,181,832	2,712,227	2,555,491
Total costs and expenses	<u>3,200,359</u>	<u>2,904,919</u>	<u>6,830,171</u>	<u>6,358,446</u>
LOSS FROM OPERATIONS	<u>(3,200,359)</u>	<u>(2,904,919)</u>	<u>(6,830,171)</u>	<u>(6,358,446)</u>
OTHER INCOME:				
Gain/(Loss) on revaluation of derivative warrants	1,000	(20,000)	(3,000)	(46,950)
Interest income, net	11,798	4,228	23,969	8,882
Total other income (expense), net	<u>12,798</u>	<u>(15,772)</u>	<u>20,969</u>	<u>(38,068)</u>
NET LOSS	<u>\$ (3,187,561)</u>	<u>\$ (2,920,691)</u>	<u>\$ (6,809,202)</u>	<u>\$ (6,396,514)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.46)</u>	<u>\$ (1.69)</u>	<u>\$ (1.15)</u>	<u>\$ (3.75)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>6,963,301</u>	<u>1,731,561</u>	<u>5,935,111</u>	<u>1,706,278</u>