

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): **May 6, 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))

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

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On May 6, 2019, we issued a press release announcing our results for the three months ended March 31, 2019. A copy of the press release is furnished herewith as Exhibit 99.1.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

<u>Number</u>	<u>Title</u>
<u>99.1</u>	<u>Press release dated May 6, 2019, titled "Collectar Reports 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: May 6, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Charles T. Bernhardt

Name: Charles T. Bernhardt

Title: Interim Chief Financial Officer



Cellecstar Reports First Quarter 2019 Financial Results and Provides a Corporate Update

Reported positive top-line results from relapsed/refractory multiple myeloma cohort in ongoing Phase 2 clinical study of CLR 131

Announced median overall survival rate of 22 months in Cohorts 1-4 in its ongoing Phase 1 clinical study of CLR 131 in relapsed/refractory multiple myeloma

Initiated a Phase 1 pediatric study for the treatment of select relapsed or refractory solid tumors, including neuroblastoma, lymphomas and malignant brain tumors

FLORHAM PARK, N.J., May 06, 2019 -- 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 first quarter ended March 31, 2019, and provided a corporate update.

First Quarter and Recent Corporate Highlights

- Announced additional positive top-line results from a relapsed/refractory multiple myeloma cohort in the ongoing Phase 2 clinical study of CLR 131, the Company's lead product candidate. In the cohort, CLR 131 achieved a 30% overall response rate in the first 10 evaluable patients. Patients received one 30-minute infusion of 25mCi/m² and CLR 131 represented, on average, seventh line treatment. The Company previously announced an overall response rate of 33% as the fourth line average treatment in patients with R/R diffuse large B-cell lymphoma (DLBCL) also receiving the single, 25mCi/m² dose of CLR 131.
 - Announced median overall survival (mOS) of 22 months in Cohorts 1-4 of the Company's ongoing Phase 1 clinical trial evaluating CLR 131 for the treatment of relapsed/refractory multiple myeloma. The mOS results were from 15 patients, all of whom were heavily pretreated and averaged five prior lines of systemic therapy.
 - Received an exemption from the U.S. Food and Drug Administration (FDA) to the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC) for the use of CLR 131 in connection with the Company's pediatric Investigational New Drug Application (IND). This exemption has allowed Cellecstar to initiate patient enrollment in its Phase 1 pediatric study for the treatment of select relapsed or refractory solid tumors including neuroblastoma, lymphomas and malignant brain tumors.
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“The data we have seen thus far for CLR 131 are very compelling with demonstrated activity in at least 3 hematologic cancers. We continue to make significant progress in the clinic and are excited to now provide this promising treatment to pediatric cancer patients,” said James Caruso, president and CEO of Collectar. “We believe CLR 131 has the potential to be a meaningful part of the treatment regimen for patients battling life-threatening cancers and look forward to continuing to provide updates on our studies throughout 2019.”

First Quarter Financial Highlights

Research and Development Expense: Research and development expense for the three months ended March 31, 2019 was \$2.3 million, compared to \$2.1 million in the three months ended March 31, 2018. The overall increase in research and development expense of \$184,000, or 8%, was primarily a result of an increase in clinical project costs of approximately \$285,000 related to the start-up of the pediatric study. Manufacturing and related costs increased as a result of an increase in patient recruitments for the on-going clinical trials. Pre-clinical studies decreased as some studies were concluding. The general research and development costs were relatively consistent.

General and Administrative Expense: General and administrative expense for the three months ended March 31, 2019 was approximately \$1,321,000, compared to approximately \$1,329,000 in the three months ended March 31, 2018 and remained relatively consistent.

Net Loss: Net loss for the three months ended March 31, 2019 was \$(3.6) million, or a loss of \$(0.76) per diluted share, compared to a net loss of \$(3.5) million, or a loss of \$(2.07) per diluted share, in the three months ended March 31, 2018.

Cash and Cash Equivalents: As of March 31, 2019, cash and cash equivalents were approximately \$10.5 million compared to \$13.3 million as of December 31, 2018. The Company believes this cash balance is adequate to fund our pipeline development and operations into the first quarter 2020.

About CLR 131

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic PDC (proprietary phospholipid drug conjugate) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing’s sarcoma and osteosarcoma. The FDA previously accepted our IND application for a Phase 1 open-label, dose-escalating study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin’s lymphoma) and malignant brain tumors.

About Celectar Biosciences, Inc.

Celectar Biosciences is focused on the discovery, development, and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and to broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 2 clinical study in R/R MM and select B-cell malignancies, as well as a dose escalation Phase 1 study in patients with R/R MM. The company is initiating a Phase 1 study with CLR 131 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.celectar.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. 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

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,488,288	\$ 13,255,616
Restricted cash	—	55,000
Prepaid expenses and other current assets	604,650	641,218
Total current assets	11,092,938	13,951,834
Fixed assets, net	516,847	543,339
Right-of-use asset, net	392,122	—
Long-term assets	540,823	540,823
Other assets	6,214	18,086
TOTAL ASSETS	\$ 12,548,944	\$ 15,054,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,055,074	\$ 1,543,819
Derivative liability	47,000	43,000
Capital lease obligations, current portion	1,402	2,213
Deferred rent	—	33,090
Lease liability	96,287	—
Total current liabilities	2,199,763	1,622,122
LONG-TERM LIABILITIES:		
Deferred rent, less current portion	—	170,999
Lease liability	502,207	—
Total long-term liabilities	502,207	170,999
TOTAL LIABILITIES	2,701,970	1,793,121
STOCKHOLDERS' EQUITY:		
Series C preferred stock: 335 and 473 issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	1,789,062	2,526,049
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 5,086,709 and 4,732,387 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	51	47
Additional paid-in capital	109,267,845	108,323,208
Accumulated deficit	(101,209,984)	(97,588,343)
Total stockholders' equity	9,846,974	13,260,961
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 12,548,944	\$ 15,054,082

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

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
COSTS AND EXPENSES:		
Research and development	\$ 2,308,397	\$ 2,124,060
General and administrative	<u>1,321,415</u>	<u>1,329,467</u>
Total costs and expenses	<u>3,629,812</u>	<u>3,453,527</u>
LOSS FROM OPERATIONS	<u>(3,629,812)</u>	<u>(3,453,527)</u>
OTHER INCOME (EXPENSE):		
Loss on revaluation of derivative warrants	(4,000)	(26,950)
Interest income, net	<u>12,171</u>	<u>4,654</u>
Total other income (expense), net	<u>8,171</u>	<u>(22,296)</u>
NET LOSS	<u>\$ (3,621,641)</u>	<u>\$ (3,475,823)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.76)</u>	<u>\$ (2.07)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>4,773,500</u>	<u>1,680,818</u>