

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): **March 2, 2021**

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 March 2, 2021, we issued a press release announcing our results for the year ended December 31, 2020 and provided a corporate update. 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 March 2, 2021, titled "Cellecstar Reports Financial Results for Year Ended December 31, 2020 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: March 2, 2021

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Cellecstar Reports Financial Results for Year Ended December 31, 2020 and Provides a Corporate Update

FLORHAM PARK, N.J., March 2, 2021 -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced financial results for the year ended December 31, 2020 and provided a corporate update.

Fourth Quarter and Recent Corporate Highlights

- Received Orphan Drug Designation from the European Commission for CLR 131 in Waldenstrom's macroglobulinemia (WM) which provides certain benefits including protocol assistance, reduced EU regulatory filing fees and 10 years of European market exclusivity
- Initiated pivotal study of CLR 131 in Waldenstrom's macroglobulinemia (CLOVER-WaM)
 - o Pivotal study is designed as a global, non-comparator, single arm, expansion cohort of the currently ongoing Phase 2 CLOVER-1 study of CLR 131 and is in alignment with feedback received from the U.S. Food and Drug Administration from the September 2020 guidance meeting
 - o The study will enroll 50 WM patients who have failed first-line therapy, have failed to respond to a BTK inhibitor (i.e., ibrutinib) or had a suboptimal response
 - o The primary endpoint of the study is response rate defined as a partial response or better (a minimum of a 50% reduction in the biological marker IgM)
- Announced Closing of \$45.0 Million Underwritten Public Offering and Concurrent Private Placement
- Announced CLR 131 demonstrated preliminary activity in inoperable brain tumors in an international open label, dose escalation Phase 1 safety study of children and adolescents with relapsed or refractory cancers, specifically high-grade gliomas, high risk neuroblastomas and select soft tissue sarcomas
 - o CLR 131 was measured in brain tumors, confirming that systemic administration of CLR 131 crosses the blood brain barrier and is delivered into tumors
 - o Initial activity was expected to occur at doses of 60 mCi/m² and higher; disease control has been noted at lower dose levels in heavily pretreated patients with ependymomas

"2020 was an important year for Cellecstar, having announced key data from our Phase 2a CLOVER-1 study; having gained clarity on our Waldenstrom's macroglobulinemia regulatory strategy after a positive meeting with the FDA in the Fall; and having completed a successful capital raise to support our WM pivotal study to our anticipated marketing approval date," said James Caruso, president and CEO of Cellecstar. "We are fully engaged in the execution our CLR 131 clinical programs, prioritizing the WM pivotal study, enriching our refractory multiple myeloma data sets, and advancing our pediatric study. In parallel, we continue our research to better understand the unique potential of our delivery platform and look forward to sharing additional data."

2020 Financial Highlights

Cash and Cash Equivalents: As of December 31, 2020, the company had cash and cash equivalents of \$57.2 million compared to \$10.6 million at December 31, 2019. Cash provided by financing activities was \$60.5 million, offset by cash used in operating activities of \$13.9 million. The company believes its cash on hand is adequate to fund basic budgeted operations for at least 12 months from the filing of these financial statements.

Research and Development Expense: Research and development expense for the year ended December 31, 2020 was \$10.1 million, compared to \$9.0 million for the year ended December 31, 2019. The overall increase in research and development expense of approximately 13% was primarily attributable to an increase in general research and development costs resulting from increased personnel-related costs. Manufacturing and related costs decreased due to a reduction in materials production processes and related costs. Clinical and pre-clinical project costs were relatively consistent.

General and Administrative Expense: General and administrative expense for the year ended December 31, 2020 was \$5.1 million, compared to \$5.2 million for the year ended December 31, 2019. The decrease of approximately 1% in general and administrative costs was primarily related to a decrease in personnel and public company expenses offset by an increase in legal fees and business insurance.

Net Loss: The net loss attributable to common stockholders for the year ended December 31, 2020 was (\$15.1) million, or (\$0.76) per share, compared to (\$14.1) million, or (\$1.84) per share, in 2019.

About Cellecstar Biosciences, Inc.

Cellecstar 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 product pipeline includes CLR 131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while

limiting exposure to healthy cells unlike many traditional on-market treatment options. CLR 131, is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) Waldenström's macroglobulinemia, a Phase 2b study in r/r multiple myeloma patients, the CLOVER-2 Phase 1 study for a variety of pediatric cancers, 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 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 and our Form 10-K for the year ended December 31, 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.

Contacts

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CELLECTAR BIOSCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 57,165,377	\$ 10,614,722
Prepaid expenses and other current assets	774,432	770,951
Total current assets	57,939,809	11,385,673
Fixed assets, net	355,982	435,083
Right-of-use asset, net	282,365	348,841
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 58,659,370	\$ 12,250,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,443,197	\$ 2,663,873
Lease liability	119,904	105,885
Total current liabilities	3,563,101	2,769,758
LONG-TERM LIABILITIES:		
Lease liability	301,740	421,644
Total long-term liabilities	301,740	421,644
TOTAL LIABILITIES	3,864,841	3,191,402
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized;		
Series C preferred stock: 215 issued and outstanding as of both December 31, 2020 and 2019	1,148,204	1,148,204
Series D preferred stock: 1,519 and 0 issued and outstanding as of December 31, 2020 and 2019, respectively	18,887,645	—
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 45,442,729 and 9,386,689 shares issued and outstanding at December 31, 2020 and 2019, respectively	454	94
Additional paid-in capital	161,533,653	119,592,366
Accumulated deficit	(126,775,427)	(111,681,255)
Total stockholders' equity	54,794,529	9,059,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 58,659,370	\$ 12,250,811

CELLECTAR BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2020	2019
COSTS AND EXPENSES:		
Research and development	\$ 10,140,681	\$ 8,996,058
General and administrative	5,149,668	5,182,566
Total costs and expenses	15,290,349	14,178,624
LOSS FROM OPERATIONS	(15,290,349)	(14,178,624)
OTHER INCOME:		
Gain on revaluation of derivative warrants	—	43,000
Gain on extinguishment of debt	185,280	—
Interest income, net	10,897	42,712
Total other income, net	196,177	85,712
NET LOSS	\$ (15,094,172)	\$ (14,092,912)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (0.76)	\$ (1.84)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	19,812,659	7,675,092