

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): **June 4, 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 7.01 REGULATION FD DISCLOSURE

On June 4, 2021, we issued a press release announcing that we presented a poster at the American Society of Clinical Oncology (ASCO) Annual meeting. In conjunction with the poster presentation, our management will host a KOL call with the lead investigator for our Phase 2 CLOVER-1 study of CLR 131 in patients with relapsed/refractory B-cell hematologic cancers, Dr. Sikander Ailawadhi, M.D. of the Mayo Clinic. 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
<u>99.1</u>	<u>Press release dated June 4, 2021, titled "Cellectar Presents Data in Waldenström's Macroglobulinemia in Poster at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting"</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: June 4, 2021

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer



Collectar Presents Data in Waldenstrom's Macroglobulinemia in Poster at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

Mean treatment free remission 1.1 years and remains ongoing

Progression free survival for MYD88 wild type and high-risk patients 18 months and ongoing

FLORHAM PARK, N.J., June 4, 2021 -- Collectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, today presented a poster at the American Society of Clinical Oncology (ASCO) Annual meeting. In conjunction with the poster presentation, management will host a KOL call with the lead investigator for the company's Phase 2 CLOVER-1 study of CLR 131 in patients with relapsed/refractory B-cell hematologic cancers, Dr. Sikander Ailawadhi, M.D. of the Mayo Clinic.

The poster presentation entitled: Treatment Free Remission (TFR) and Overall Response Rate (ORR) Results in Patients with Relapsed/Refractory Waldenstrom's Macroglobulinemia (WM) Treated with CLR 131 is an in-depth update of six patients from the company's Phase 2a study of CLR 131 in Waldenstrom's macroglobulinemia. To date, data have shown:

- 100% (6/6) overall response rate, 83.3% (5/6) major response rate and a 16.7% (1/6) complete response rate
- Median time to initial response was 22 days after first infusion
- Median time to major response, as defined as at least a 50% reduction in IgM, was 44 days after first infusion
- Mean treatment free remission, as defined as the time from the last CLR 131 infusion to progression of disease, is 1.1 years and remains ongoing
- Duration of response has not been reached, with 100% of the MYD88 wild type and high risk patients exceeding 8.5 months
- Progression free survival (PFS) for both MYD88 wild type patients as well as the high-risk subgroup has not been reached after 18 months; PFS for multidrug refractory patients was 11 months
- The most frequently reported treatment emergent adverse events were cytopenias

"CLR 131 is a differentiated targeted radiotherapy that has the potential to address patients with any mutational status, risk profile or multi-drug refractoriness in WM. Our pivotal study strategy will leverage these properties to address the treatment needs of patients, including the potential to provide durable response rates and meaningful treatment-free remission," said Dr. John Friend, chief medical officer at Collectar. "CLR 131 has demonstrated impressive results including, to our knowledge, the only monotherapy to result in a complete response in this challenging WM patient set."

James Caruso, president and CEO of Collectar added, "The data presented today from our ongoing Phase 2 CLOVER-1 study of CLR 131 in Waldenstrom's further validates our clinical development program and gives us confidence in our goal of providing a new and better treatment with the potential to prolong and improve the quality of life for patients suffering from this devastating disease."

Management will host a conference call and webcast today, June 4, at 10:00 am ET featuring key opinion leader Dr. Sikander Ailawadhi. Dr. Ailawadhi is a Professor of Medicine, Lead, International Cancer Center, Division of Hematology/Oncology, Departments of Medicine and Cancer Biology at Mayo Clinic Florida. He was awarded the 2013 NCI Cancer Clinical Investigator Team Leadership Award as an Assistant Professor of Medicine at the USC Norris Comprehensive Cancer Center. Subsequently, he joined the Division of Hematology and Oncology at Mayo Clinic in Florida as a Senior Consultant in order pursue his career goal of clinical, translational and outcomes-based research in B-cell malignancies.

Dial-in & Webcast information

Domestic: 877-705-6003
 International: 201-493-6725
 Conference ID: 13719983
 Webcast: <http://public.viavid.com/index.php?id=145036>

A replay of the call will be available on the [Events](#) page of company website following the live event.

About the Pivotal Trial of CLR 131 in Waldenstrom's macroglobulinemia (WM)

The pivotal trial is designed as a global, non-comparator, single arm, expansion cohort of the currently ongoing Phase 2 CLOVER-1 study of CLR 131. The study will enroll 50 WM patients. Patients in the trial will receive up to four doses of CLR 131 over two cycles (cycle one days 1, 15, and cycle two days 57, 71). The primary endpoint of the trial is response rate as defined as a partial response (a minimum of a 50% reduction in the biological marker IgM) or better in patients that receive a minimum total body dose of 60 mCi with secondary endpoints of treatment free survival, duration of response and progression free survival. An independent data monitoring committee (iDMC) will perform an interim safety and futility evaluation on the first 10 patients enrolled. The assessment will occur patient by patient and will conclude after the tenth patient is evaluated; there is no planned study stoppage.

About Waldenstrom's macroglobulinemia

Waldenstrom's macroglobulinemia (WM) is a rare and incurable disease defined by specific genotypic subtypes that defines patient responses and long-term outcomes. The annual incidence is 6,500 with prevalence of approximately 60,000 patients globally. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which normally matures into a plasma cell whose job is to manufacture immunoglobulins (antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and other tissues and organs of the lymphatic system. These clonal cells over-produce an antibody of a specific class called IgM.

WM cells have characteristics of both cancerous B-lymphocytes (NHL) and plasma cells (multiple myeloma), and they are called lymphoplasmacytic cells. For that reason, WM is classified as a type of non-Hodgkin's lymphoma called lymphoplasmacytic lymphoma (LPL). About 95% of LPL cases are WM; the remaining 5% do not secrete IgM and consequently are not classified as WM.

There is no standard treatment for WM. Several drugs have demonstrated activity either alone or in combinations, but only a single drug has received regulatory approval. Treatment is mainly focused on the control of symptoms and the prevention of organ damage. Front-line treatments for WM include rituximab alone or in combination with other agents. In the salvage therapy (second line or later) setting, ibrutinib, combinations of proteasome inhibitors and immunomodulatory drugs and stem cell transplantation are considered. Ibrutinib is the only drug to receive regulatory approval (2015) as a salvage therapy; in late 2019, it was approved for front-line treatment in combination with rituximab. Factors such as long-term cytopenias, age, hyper viscosity, the need for quick disease control, lymphadenopathy, co-morbidities, and IgM-related end-organ damage are key consideration in the choice of treatment.

About Cellectar Biosciences, Inc.

Cellectar 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 CLR 131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit www.cellectar.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 any potential 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, 2020. 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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