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 18, 2021**

CELLECTAR BIOSCIENCES, INC.

(*Exact name of registrant as specified in its charter*)

Delaware	**1-36598**	**04-3321804**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(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 August 18, 2021, we issued a press release announcing that we have been awarded a peer-reviewed National Institutes of Health (NIH) Phase II Small Business Innovation Research (SBIR) grant of approximately $2 Million from the National Cancer Institute (NCI). 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
99.1	Press release dated August 18, 2021, titled "Cellectar Awarded $2.0 Million Phase II NIH SBIR Grant to Support Pivotal Study of Iopofosine I-131 in Waldenstrom's Macroglobulinemia"
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

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 18, 2021

CELLECTAR BIOSCIENCES, INC.

By: */s/ Dov Elefant*
Name: Dov Elefant
Title: Chief Financial Officer

Exhibit 99.1

Cellectar Awarded $2.0 Million Phase II NIH SBIR Grant to Support Pivotal Study of Iopofosine I-131 in Waldenstrom's Macroglobulinemia

FLORHAM PARK, N.J., August 18, 2021 -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, today announced it has been awarded a peer-reviewed National Institutes of Health (NIH) Phase II Small Business Innovation Research (SBIR) grant of approximately $2 Million from the National Cancer Institute (NCI).

The company is currently conducting a global pivotal study of iopofosine I-131 (also known as CLR 131) in Waldenstrom's macroglobulinemia (WM) patients who have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitor failed or suboptimal response patients. The study was initiated in January of 2021 and is expected to take approximately 18 months to fully enroll.

"We appreciate the recognition and funding that the NIH and NCI have chosen to provide Cellectar for our pivotal iopofosine program. WM is an incurable disease with existing treatment options restricted to one approved drug and various unapproved salvage therapies." said James Caruso, president and CEO of Cellectar. "This $2 million non-dilutive grant will be used to support and accelerate the ongoing pivotal study. With the addition of this grant and over $46.8 million in cash and cash equivalents as of June 30, 2021, we are well capitalized with a forecasted cash runway into Q3 2023 which we believe will take us through top-line data and submission of the NDA."

The company has received FDA Fast Track Designation and was granted Orphan Drug Designation in the U.S. and EU for WM. At ASCO this year, compelling iopofosine I-131 data were presented on six WM patients, which demonstrated a 100% overall response rate. A copy of the abstract, entitled: *Treatment Free Remission (TFR) and Overall Response Rate (ORR) Results in Patients with Relapsed/Refractory Waldenstrom's Macroglobulinemia (WM) Treated with iopofosine I-131* is available on ASCO's website here.

About the Pivotal Study of iopofosine I-131 in Waldenstrom's macroglobulinemia

The pivotal study is designed as a global, non-comparator, single arm, expansion cohort of the currently ongoing Phase 2 CLOVER-1 study of iopofosine I-131. The study will enroll 50 WM patients. Patients in the study will receive up to four doses of iopofosine I-131 over two cycles (cycle one days 1, 15, and cycle two days 57, 71). The primary endpoint of the study 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. The study will include WM patients who have received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitor failed or suboptimal response patients. To learn more about the clinical study please visit www.wmclinicaltrial.com.

About Waldenstrom's macroglobulinemia

Waldenstrom's macroglobulinemia 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 proteosome 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 iopofosine I-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 and www.wmclinicaltrial.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 iopofosine I-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 iopofosine I-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

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