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): October 18, 2023

Caribou Biosciences, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40631**	**45-3728228**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2929 7th Street, Suite 105 Berkeley, California		**94710**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (510) 982-6030

N/A
(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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, $0.0001 par value per share	CRBU	NASDAQ Global Select 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 October 18, 2023, Caribou Biosciences, Inc. (the "Company") issued a press release announcing that it has received clearance of its investigational new drug (“IND”) application from the U.S. Food and Drug Administration (“FDA”) for CB-012, an allogeneic anti-C-type lectin-like molecule-1 (anti-"CLL-1") CAR-T cell therapy. CB-012 will be evaluated in the multicenter, open-label, AMpLify phase 1 clinical trial for patients with relapsed or refractory acute myeloid leukemia ("r/r AML"). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and also is incorporated by reference into this Item 7.01.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing or other document under the Exchange Act or the Securities Act of 1933, as amended (the “Securities Act”), regardless of any general incorporation language in any such filing or document, except as shall be expressly set forth by specific reference in any such filing or document.

Item 8.01 Other Events.

On October 18, 2023, the Company announced that it has received clearance of its IND application from the FDA for CB-012, an allogeneic CAR-T cell therapy targeting CLL-1. CB-012 will be evaluated in the multicenter, open-label, AMpLify phase 1 clinical trial for patients with r/r AML.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Caribou Biosciences, Inc. on October 18, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Caribou Biosciences, Inc.

Date: October 18, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Announces FDA Clearance of IND Application for CB-012, an Allogeneic Anti-CLL-1 CAR-T Cell Therapy for the Treatment of Relapsed or Refractory Acute Myeloid Leukemia

-- AMpLify Phase 1 clinical trial to initiate patient enrollment by mid-2024 --

-- CB-012 is the first allogeneic CAR-T cell therapy with both checkpoint disruption and immune cloaking to enter the clinic --

BERKELEY, CA, October 18, 2023– Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today announced that it received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) for CB-012, an allogeneic anti-C-type lectin-like molecule-1 (anti-CLL-1) CAR-T cell therapy. CB-012 will be evaluated in the multicenter, open-label, AMpLify Phase 1 clinical trial for patients with relapsed or refractory acute myeloid leukemia (r/r AML).

“Clearance of our IND application for CB-012 represents another significant milestone for Caribou as our third off-the-shelf CAR-T cell therapy enters the clinic,” said Rachel Haurwitz, PhD, Caribou’s president and chief executive officer. “We look forward to initiating patient enrollment in the AMpLify Phase 1 trial by the middle of 2024 to evaluate the safety and tolerability of CB-012 in patients suffering from AML.”

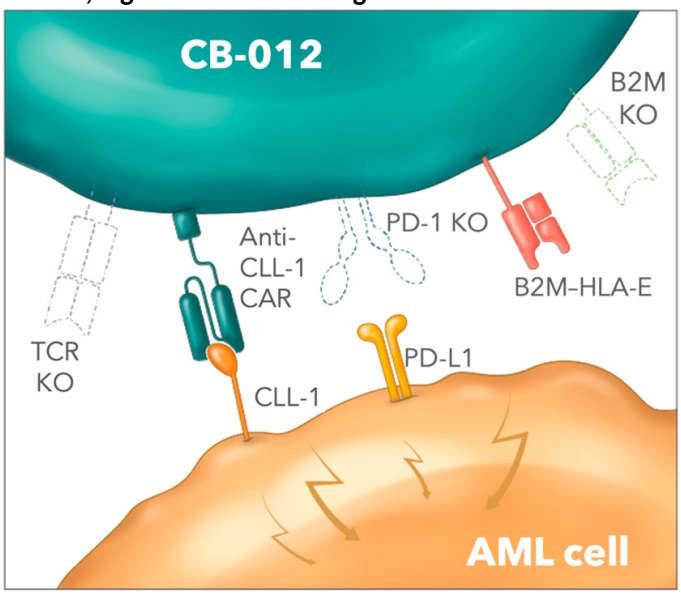
CLL-1 is a compelling therapeutic target because it is highly expressed on AML cells and leukemic stem cells, but it is not expressed on hematopoietic stem cells.

“There is an urgent need to develop new treatments for patients with relapsed or refractory AML, for which the treatment options are predominantly limited to salvage chemotherapy regimens,” said Naval Daver, MD, associate professor and director, Department of Leukemia, The University of Texas MD Anderson Cancer Center. “An allogeneic CAR-T cell therapy that could safely and effectively target AML blasts while preserving healthy hematopoietic stem cells could provide a much-needed off-the-shelf option for these patients.”

Caribou’s patented next-generation CRISPR Cas12a chRDNA genome-editing technology platform maintains high genomic integrity and significantly improves the specificity of genome editing.

“CB-012 was engineered with five genome edits, and is the first allogeneic CAR-T cell therapy, to our knowledge, with both checkpoint disruption through a PD-1 knockout, and immune cloaking through a B2M knockout and B2M–HLA-E fusion transgene insertion,” said Steve Kanner, PhD, Caribou’s chief scientific officer. “Both armoring strategies are designed to improve the antitumor activity of CB-012 that we believe are crucial for targeting this difficult to treat indication.”

CB-012, a genome-edited allogeneic anti-CLL-1 CAR-T cell therapy with both checkpoint disruption and immune cloaking



A photo accompanying this announcement is available at https://pr.globenewswire.com/FileDownloader/DownloadFile?source=pnr&fileGuid=54559479-fba4-4f88-a241-583814242f44

About the AMpLify trial

The AMpLify Phase 1 trial is an open-label, multicenter clinical trial designed to evaluate CB-012 in adult patients with relapsed or refractory acute myeloid leukemia (r/r AML). Part A, a 3+3 dose escalation design, will evaluate the safety and tolerability of CB-012 at ascending dose levels to determine the maximum tolerated dose and/or the recommended doses for expansion. Part B is the dose expansion portion with the primary objective of determining antitumor response, assessed by overall response rate (ORR), after a single dose of CB-012. AMpLify will include patients who have not responded to or relapsed after standard treatment and will exclude patients who have been treated with more than 3 prior lines of therapy and patients with proliferative disease. Caribou plans to initiate patient enrollment in the AMpLify trial to treat patients with a single administration of CB-012 at dose level 1 ($25x10^6$ CAR-T cells) by mid-2024.

About acute myeloid leukemia

Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. It is estimated there will be 20,380 new cases of AML in the United States in 2023. The five-year survival rate for these patients is approximately 30%. AML is currently treated with chemotherapy, targeted therapies, and/or allogeneic or autologous stem cell transplant. For patients with relapsed or refractory AML, there are few treatment options and median overall survival is typically less than seven months.

About Caribou's novel next-generation CRISPR platform

CRISPR genome editing uses easily designed, modular biological tools to make DNA changes in living cells. There are two basic components of Class 2 CRISPR systems: the nuclease protein that cuts DNA and the RNA molecule(s) that guide the nuclease to generate a site-specific, double-stranded break, leading to an edit at the targeted genomic site. CRISPR systems are capable of editing unintended genomic sites, known as off-target editing, which may lead to harmful effects on cellular function and phenotype. In response to this challenge, Caribou has developed CRISPR hybrid RNA-DNA guides (chRDNAs; pronounced "chardonnays") that direct substantially more precise genome editing compared to all-RNA guides. Caribou is deploying the power of its Cas12a chRDNA technology to carry out high efficiency multiple edits, including multiplex gene insertions, to develop CRISPR-edited therapies.

About Caribou Biosciences, Inc.

Caribou Biosciences is a clinical-stage CRISPR genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. The company's genome-editing platform, including its Cas12a chRDNA technology, enables superior precision to develop cell therapies that are armored to potentially improve antitumor activity. Caribou is advancing a pipeline of off-the-shelf cell therapies from its CAR-T and CAR-NK platforms as readily available treatments for patients with hematologic malignancies and solid tumors. Follow us @CaribouBio and visit www.cariboubio.com.

Forward-looking statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements related to Caribou's strategy, plans, and objectives, and expectations regarding its clinical and preclinical development programs, including its expectations relating to the timing of initiating patient enrollment in the AMpLify Phase 1 clinical trial for CB-012. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements are subject to risks and uncertainties, and actual results may differ materially from any future results expressed or implied by the forward-looking statements. Risks and uncertainties include, without limitation, risks inherent in the development of cell therapy products; uncertainties related to the initiation, cost, timing, progress, and results of Caribou's current and future research and development programs, preclinical studies, and clinical trials; and the risk that initial, preliminary, or interim clinical trial data will not ultimately be predictive of the safety and efficacy of Caribou's product candidates or that clinical outcomes may differ as patient enrollment continues and as more patient data becomes available; the risk that preclinical study results observed will not be borne out in human patients or different conclusions or considerations are reached once additional data have been received and fully evaluated; as well as other risk factors described from time to time in Caribou's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, Caribou undertakes no obligation to update publicly any forward-looking statements for any reason.

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