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 29, 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 March 29, 2023, Caribou Biosciences, Inc. (the "Company" or "Caribou") issued a press release announcing that it has initiated the dose expansion portion of the CB-010 ANTLER phase 1 trial in second-line patients with large B cell lymphoma ("LBCL") following the recent completion of the dose escalation portion of the ANTLER trial. 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, 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 Matters.

On March 29, 2023, the Company announced that it has initiated the dose expansion portion of the CB-010 ANTLER phase 1 trial in second-line patients with LBCL following the recent completion of the dose escalation portion of the ANTLER trial. In ANTLER dose expansion, the Company plans to evaluate two different dose levels of CB-010, each evaluated as a single-dose regimen ($80x10^6$ CAR-T cells and $120x10^6$ CAR-T cells) in approximately 30 total second-line patients (approximately 15 patients per dose level) to determine the recommended phase 2 dose (the "RP2D"). Once the RP2D is determined, the Company may enroll additional patients, including patients who have received prior CD19-targeted therapies. The Company expects the collective data from ANTLER will inform a potential pivotal trial plan. The Company also expects to provide an ANTLER trial safety and efficacy data update in the second half of 2023, including data from at least 15 patients from dose escalation with a minimum of 6 months of follow up.

In ANTLER dose escalation, in which the Company has been treating patients following a minimum of two prior lines of therapy or primary refractory patients, CB-010 was generally well-tolerated at all three dose levels evaluated with adverse events consistent with autologous or allogeneic anti-CD19 CAR-T cell therapies. Most recently, CB-010 at dose level 3 ($120x10^6$ CAR-T cells) has demonstrated an encouraging safety profile with no dose-limiting toxicities ("DLTs") in the three patients treated.

Forward-Looking Statements

This Form 8-K 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 results and updates from its ANTLER phase 1 clinical trial for CB-010, its plans for dose expansion, its ability to enroll second-line patients, its determination of RP2D, and its enrollment of sufficient patients to inform a potential pivotal trial plan. 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 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 more patient data becomes available; the risk that preclinical study results we observed will not be borne out in human patients; 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Caribou Biosciences, Inc. on March 29, 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: March 29, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Initiates Dose Expansion Portion of CB-010 ANTLER Phase 1 Trial in Second-line LBCL Patients

-- CB-010 is the first allogeneic CAR-T cell therapy, to Caribou's knowledge, to be evaluated clinically in second-line LBCL patients --

-- Next ANTLER update planned for H2 2023 --

BERKELEY, CA, March 29, 2023 – Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today announced initiation of the dose expansion portion of the CB-010 ANTLER Phase 1 trial in second-line patients with large B cell lymphoma (LBCL) following the recent completion of dose escalation. CB-010 is an allogeneic cell therapy being evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL).

"The ANTLER trial continues to push boundaries in evaluating the potential of allogeneic CAR-T therapies as we proceed with the dose expansion portion of ANTLER, which will now dose second-line patients with LBCL," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "To our knowledge, CB-010 is the first allogeneic CAR-T cell therapy to be evaluated clinically in the second-line setting, where we aim to provide access to greater numbers of patients and potentially impact outcomes earlier in the course of their disease. We remain focused on our goal to develop an allogeneic cell therapy that meaningfully rivals autologous cell therapies and extends the potential reach of cell therapy treatment options for patients."

In ANTLER dose escalation, CB-010 was generally well tolerated at all 3 dose levels evaluated, demonstrating an encouraging safety profile. The observed adverse events were consistent with autologous or allogeneic anti-CD19 CAR-T cell therapies. Most recently, no dose-limiting toxicities (DLTs) were observed in the 3 patients treated with CB-010 at dose level 3 ($120x10^6$ CAR-T cells). As previously reported, at dose level 1 ($40x10^6$ CAR-T cells), 6 of the 6 patients in cohort 1 achieved a complete response as best response, 3 of the 6 patients maintained their complete response at 6 months, and 2 of the 6 patients maintained their complete response at 12 months. In dose escalation, ANTLER enrolled patients following a minimum of two prior lines of therapy as well as primary refractory patients.

"We have heard time and again from the lymphoma community about the challenges of autologous CAR-Ts, such as apheresis, bridging therapy, long wait times for manufacturing, or manufacturing failures. CB-010 addresses these challenges as the therapy is manufactured from healthy donor cells and is available off-the-shelf for eligible clinical trial patients," said Syed Rizvi, MD, Caribou's chief medical officer. "Evaluating CB-010 in the second-line setting places Caribou at the forefront of the off-the-shelf cell therapy field by potentially addressing the unmet needs of patients with a readily available therapeutic option at an earlier stage of their disease."

In the ANTLER dose expansion portion, Caribou plans to evaluate 2 different dose levels of CB-010, each evaluated as a single-dose regimen ($80x10^6$ CAR-T cells and $120x10^6$ CAR-T cells), in approximately 30 total second-line patients (approximately 15 patients per dose level) to determine the recommended Phase 2 dose (RP2D). Once the RP2D is determined, Caribou may enroll additional patients, including patients who have failed prior CD19-targeted therapies. Caribou expects the

collective data from ANTLER will inform a potential pivotal trial plan. Caribou expects to provide an ANTLER trial safety and efficacy data update in H2 2023, including data from at least 15 patients from dose escalation with a minimum of 6 months of follow up.

About CB-010

CB-010 is the lead product candidate from Caribou's allogeneic CAR-T cell therapy platform and is being evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). In the ongoing ANTLER Phase 1 trial, Caribou is enrolling second-line patients with large B cell lymphoma (LBCL) comprising 4 different subtypes of aggressive r/r B-NHL (DLBCL NOS, PMBCL, HGBL, and transformed FL). CB-010 is an allogeneic anti-CD19 CAR-T cell therapy engineered using Cas9 CRISPR hybrid RNA-DNA (chRDNA) technology. CB-010 is the first allogeneic anti-CD19 CAR-T cell therapy in the clinic, to Caribou's knowledge, with a PD-1 knockout (KO), a genome-editing strategy designed to improve antitumor activity by limiting premature CAR-T cell exhaustion. CB-010 is also the first allogeneic CAR-T cell therapy, to Caribou's knowledge, to be evaluated clinically in the second-line setting and has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations. Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov.

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 proprietary 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

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updates from its ANTLER Phase 1 clinical trial for CB-010, its plans for dose expansion, its ability to enroll second-line patients, its determination of RP2D, and its enrollment of sufficient patients to inform a potential pivotal trial plan. 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 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 more patient data becomes available; the risk that preclinical study results we observed will not be borne out in human patients; 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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