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): December 11, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Syed Rizvi, M.D., the Chief Medical Officer of Caribou Biosciences, Inc. (the "Company"), will be leaving the Company effective December 31, 2023. Pursuant to Dr. Rizvi's Officer Employment Agreement with the Company (listed as Exhibit 10.49 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022), Dr. Rizvi will become entitled to certain payments and benefits in connection with his termination of employment contingent upon the conditions set forth in the Officer Employment Agreement, including execution and effectiveness of a separation agreement with release of claims in favor of the Company. A search is under way for a new Chief Medical Officer.

Item 7.01 Regulation FD Disclosure.

On December 12, 2023, the Company issued a press release announcing that it had received feedback from the U.S. Food and Drug Administration (the "FDA") on a phase 3 randomized controlled trial for CB-010, the Company's genome-edited allogeneic anti-CD19 CAR-T cell therapy in development for patients with second-line relapsed or refractory large B cell lymphoma ("r/r LBCL"). 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 December 12, 2023, the Company announced that it had received feedback from the FDA following a Type B clinical meeting and recent communications regarding the Company's genome-edited allogeneic anti-CD19 CAR-T cell therapy, CB-010, in development for patients with second-line r/r LBCL. The FDA provided feedback on a phase 3 randomized controlled trial for CB-010 for patients with r/r LBCL, stating that the Company's proposed comparator arm of platinum-based immunochemotherapy followed by high dose chemotherapy and autologous stem cell transplantation is acceptable. To the Company's knowledge, CB-010 is the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting. The Company plans to initiate a phase 3 pivotal trial by year-end 2024.

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements that are not historical facts are forward-looking statements. Forward-looking statements may relate to future events or future performance. These forward-looking statements are not historical facts, but rather are based on current expectations, estimates and projections about the Company, its industry, its beliefs and its assumptions. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements include, without limitation, statements related to the Company's strategy, plans, and objectives, and expectations regarding its clinical and preclinical development programs, including its expectations relating to the timing of initiating the phase 3 pivotal trial of its CB-010 product candidate. 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 the Company's current and future research and development programs, preclinical studies, and clinical trials; the risk that initial or interim clinical trial data will not ultimately be predictive of the safety and efficacy of the Company's product candidates or that clinical outcomes may differ as more patient data becomes available; the risk that preclinical study results observed will not be borne out in human patients; the risk that key regulatory input and approvals may not be obtained timely or at all; as well as other risk factors described from time to time in the Company'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, the Company 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 December 12, 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: December 12, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Provides Regulatory Update on CB-010 Pivotal Plan with Phase 3 Trial Initiation Expected by YE 2024

-- Caribou met with the FDA and reached alignment on a pivotal trial in 2L LBCL with CB-010 versus a comparator arm of immunochemotherapy followed by HDCT and ASCT --

-- ANTLER Phase 1 trial continues dose expansion enrollment; initial dose expansion data and RP2D expected Q2 2024 --

-- Caribou plans to initiate Phase 3 pivotal trial by YE 2024 --

BERKELEY, CA, December 12, 2023 – Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today provided an update based on feedback from the U.S. Food and Drug Administration (FDA) following recent communications and a Type B clinical meeting regarding the CB-010 development program. The company has received the FDA's feedback on a Phase 3 randomized controlled trial for CB-010, an allogeneic anti-CD19 CAR-T cell therapy in development for patients with second-line relapsed or refractory large B cell lymphoma (r/r LBCL). The FDA stated that Caribou's proposed comparator arm of platinum-based immunochemotherapy followed by high dose chemotherapy (HDCT) and autologous stem cell transplantation (ASCT) is acceptable.

"FDA feedback on our CB-010 pivotal development plan represents an important step in advancing our lead therapy to enable broader access of CAR-T cell therapies for patients living with large B cell lymphoma," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "As our ongoing ANTLER trial progresses, we look forward to engaging again with the FDA ahead of initiating our planned Phase 3 pivotal trial. Our goal is to establish a new second-line standard of care by delivering an off-the-shelf CAR-T cell therapy to patients as expeditiously as possible."

In the ongoing ANTLER Phase 1 trial (https://clinicaltrials.gov/study/NCT04637763), Caribou is enrolling second-line LBCL patients in the dose expansion portion based on promising data (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-positive-clinical-data-dose) from the dose escalation portion of the trial. Currently, 22 sites are active in the U.S. and the first international site is active in Australia, with additional site activation underway in the U.S. and globally. To Caribou's knowledge, CB-010 is the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting and it has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations by the FDA. In Q2 2024, the company plans to report initial dose expansion data from the ANTLER trial and share the recommended Phase 2 dose (RP2D) for CB-010. Caribou plans to initiate a Phase 3 pivotal trial with this RP2D by year-end 2024.

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) comprised of different subtypes of aggressive r/r B-NHL (DLBCL NOS, PMBCL, HGBL, tFL, and tMZL). CB-010 is an allogeneic anti-CD19 CAR-T cell therapy engineered using Cas9 CRISPR

hybrid RNA-DNA (chRDNA) genome-editing technology. To Caribou's knowledge, CB-010 is the first allogeneic CAR-T cell therapy in the clinic with a PD-1 knockout, a genome-editing strategy designed to improve antitumor activity by limiting premature CAR-T cell exhaustion. Also, to Caribou's knowledge, CB-010 is the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting and it has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations by the FDA. Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov (https://clinicaltrials.gov/study/NCT04637763).

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, objectives, and expectations regarding its clinical and preclinical development programs, including its expectations relating to the timing of initiating patient enrollment in the Phase 3 pivotal trial by year-end 2024, reporting of initial dose expansion data from the ongoing ANTLER 1 Phase 1 trial and sharing the recommended Phase 2 dose for CB-010 in Q2 2024, and the timing of updates from its ANTLER Phase 1 clinical trial for CB-010. 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; the ability to obtain key regulatory input and approvals 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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