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): April 4, 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 April 4, 2023, Caribou Biosciences, Inc. (the "Company") issued a press release announcing that CB-011, the Company's allogeneic anti-B cell maturation antigen ("BCMA") CAR-T cell therapy product candidate, has received Fast Track designation for relapsed or refractory multiple myeloma ("r/r MM") from the U.S. Food and Drug Administration ("FDA"). 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 April 4, 2023, the Company announced that its CB-011 cell therapy product candidate has received Fast Track designation for r/r MM from the FDA. CB-011 is the Company's allogeneic anti-BCMA CAR-T cell therapy incorporating an immune cloaking approach that includes both the removal of the endogenous beta-2 microglobulin ("B2M") protein and insertion of a beta-2-microglobulin–human-leukocyte-antigen-E–peptide transgene ("B2M–HLA-E"). CB-011, the Company's second product candidate, is being evaluated in the Company's ongoing CaMMouflage phase 1 clinical trial in patients with r/r MM.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Caribou Biosciences, Inc. on April 4, 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: April 4, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Announces FDA Granted Fast Track Designation to CB-011, an Allogeneic CAR-T Cell Therapy for Relapsed or Refractory Multiple Myeloma

-- CaMMouflage Phase 1 trial for CB-011 enrolling patients with r/r MM at dose level 1 --

BERKELEY, CA, April 4, 2023– Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CB-011, which is being developed for relapsed or refractory multiple myeloma (r/r MM). CB-011 is being evaluated in the company's ongoing CaMMouflage Phase 1 clinical trial in patients with r/r MM.

"Fast Track designation for CB-011 allows us instrumental interactions with the FDA as we progress our clinical development and regulatory plans for CB-011. This designation could not be more timely as we recently dosed our first patient in the CaMMouflage Phase 1 trial," said Syed Rizvi, MD, Caribou's chief medical officer. "Our goal is to develop CB-011 as a readily available off-the-shelf treatment option for patients with relapsed or refractory multiple myeloma to overcome the need for apheresis or bridging therapy, variable quality and long manufacturing timelines, manufacturing failures, or the inability to bear the burden of treatments that require frequent dosing over several months."

Fast Track designation is designed to expedite the development and review processes for promising therapeutic candidates that may fill an unmet medical need. Clinical programs with Fast Track designation may benefit from early and frequent communication with the FDA throughout the regulatory review process and may also be eligible for Accelerated Approval and Priority Review if relevant criteria are met.

About CB-011

CB-011 is the second product candidate from Caribou's allogeneic CAR-T cell therapy platform and is being evaluated in patients with relapsed or refractory multiple myeloma (r/r MM) in the CaMMouflage Phase 1 trial. CB-011 is an allogeneic anti-BCMA CAR-T cell therapy engineered using Cas12a chRDNA technology. CB-011 is the first allogeneic CAR-T cell therapy in the clinic, to Caribou's knowledge, that is engineered to improve antitumor activity through an immune cloaking strategy with a *B2M* knockout and insertion of a B2M–HLA-E fusion protein to blunt immune-mediated rejection. Additional information on the CaMMouflage trial (NCT05722418) 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 have exhibited editing at 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

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 enrollment, status, and updates from its CaMMouflage Phase 1 clinical trial for CB-011, as well as the timing of regulatory review and approval. 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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