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 31, 2026

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 31, 2026, Caribou Biosciences, Inc. (the “Company”) issued a press release announcing that it received Regenerative Medicine Advanced Therapy (“RMAT”) designation for relapsed or refractory multiple myeloma ("r/r MM") from the U.S. Food and Drug Administration (“FDA”) for CB-011, the Company's allogeneic anti-BCMA CAR-T cell therapy product candidate. 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 in this Item 7.01, including 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 otherwise subject to the liabilities of that section, 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 Events.

On March 31, 2026, the Company announced that it received RMAT designation for r/r MM from the FDA for CB-011, its allogeneic anti-BCMA CAR-T cell therapy product candidate. CB-011 is currently being evaluated in the Company’s ongoing CaMMouflage phase 1 clinical trial.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Caribou Biosciences, Inc. on March 31, 2026
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 31, 2026

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Announces the FDA Granted Regenerative Medicine Advanced Therapy (RMAT) Designation to CB-011, an Allogeneic Anti-BCMA CAR-T Cell Therapy

-- RMAT granted based on promising initial clinical data, including previously disclosed recommended dose for expansion data of 92% ORR, 75% ≥CR rate, 91% MRD negativity in the 12-patient, BCMA-naïve r/r MM patient cohort --

-- Ongoing dose expansion enrollment in CaMMouflage phase 1 clinical trial includes BCMA-naïve and BCMA-exposed cohorts; initial dose expansion and longer follow up on dose escalation data expected in 2026 --

BERKELEY, Calif., March 31, 2026 -- 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 Regenerative Medicine Advanced Therapy (RMAT) designation to CB-011 for relapsed or refractory multiple myeloma (r/r MM). CB-011, an allogeneic anti-BCMA CAR-T cell therapy, is being evaluated in the company's ongoing open-label, multicenter CaMMouflage phase 1 clinical trial evaluating patients with r/r MM.

"Only one in 10 people with multiple myeloma in the U.S. are able to receive CAR-T cell therapies due to long wait times and manufacturing limitations," said Adriana Rossi, MD, director of CAR-T and stem cell transplant clinical program at the center of excellence for multiple myeloma at Mount Sinai and an investigator on the CaMMouflage trial. "This highlights a critical gap in access for patients with relapsed or refractory disease. An off-the-shelf CAR-T cell therapy like CB-011 could help bridge that gap by offering a readily available treatment option to a broader group of patients."

As previously reported in November 2025, 48 patients have been treated in the dose escalation portion of the company's CaMMouflage phase 1 clinical trial. The $450x10^6$ CAR-T cell dose was selected as the recommended dose for expansion (RDE). In dose escalation, 12 BCMA-naïve patients were treated with the RDE; efficacy outcomes from this cohort included a 92% (11/12) overall response rate (ORR), 75% (9/12) ≥ complete response (CR) rate, and 91% (10/11 evaluable) minimal residual disease (MRD) negativity as of a September 24, 2025, data cutoff. CB-011 has demonstrated a manageable safety profile, with no cases of graft-versus-host disease, immune effector cell-associated enterocolitis, parkinsonism, or cranial nerve palsies observed at any dose level. Treatment emergent adverse events (TEAEs) in ≥25% of all patients treated with CB-011 following the selected lymphodepletion (LD) regimen (N=35) were as follows: neutropenia (80%), anemia (60%), thrombocytopenia (49%), infections (49%), dizziness (31%), cytokine release syndrome (31%), fatigue (31%), leukopenia (29%), decreased appetite (29%), constipation (26%), and pyrexia (26%) as of the data cutoff date.

"The FDA's RMAT designation for CB-011 recognizes both the significant unmet need in multiple myeloma and the encouraging clinical data we have seen so far in the CaMMouflage trial," said Tina Albertson, MD, PhD, chief medical officer at Caribou Biosciences. "The dose escalation data highlight the potential of CB-011 as the best-in-class allogeneic CAR-T cell therapy for relapsed or refractory multiple myeloma. We look forward to initiating discussion with the FDA regarding future clinical development of CB-011 and to reporting additional data this year as we continue to enroll both BCMA-naïve and BCMA-exposed patients in dose expansion."

RMAT designation is a dedicated program designed to expedite the development and review processes for promising therapeutic candidates intended to address an unmet medical need in patients with serious conditions. This designation provides important benefits in the drug development process and is designed to facilitate and expedite development and regulatory review, including providing eligibility for priority and rolling reviews and accelerated approval, if relevant criteria are satisfied.

About CB-011
CB-011 is an allogeneic anti-BCMA CAR-T cell therapy being evaluated in patients with relapsed or refractory multiple myeloma (r/r MM). To Caribou's knowledge, CB-011 is the first allogeneic CAR-T cell therapy in the clinic that is engineered to enable activity through an immune cloaking strategy with a B2M knockout and insertion of a B2M–HLA-E fusion protein to blunt immune-mediated rejection. The FDA granted CB-011 Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations for r/r MM.

About the CaMMouflage phase 1 clinical trial
The CaMMouflage clinical trial is a multicenter, open-label phase 1 trial evaluating CB-011 in adults with r/r MM who have been treated with three or more prior lines of therapy. Using a 3+3 dose escalation design, safety and efficacy of CB-011 were evaluated in 48 patients at multiple dose levels and two different lymphodepletion (LD) regimens. Thirteen patients were treated with a single dose of CB-011 ($50x10^6$ [N=3], $150x10^6$ [N=7], and $450x10^6$ [N=3] CAR-T cells) with an LD regimen of 300 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days, and 35 patients were treated with a single dose of CB-011 ($150x10^6$ [N=6], $300x10^6$ [N=13], $450x10^6$ [N=13], and $800x10^6$ [N=3] CAR-T cells) with an LD regimen of 500 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days. The ongoing dose expansion portion of the trial will evaluate safety and efficacy of CB-011 at $450x10^6$ CAR-T cells with the selected LD of 500 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days. Additional information on the CaMMouflage trial (NCT05722418) can be found at www.clinicaltrials.gov.

About Caribou Biosciences, Inc.
Caribou is a clinical-stage CRISPR genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. Caribou's genome-editing platform based on its chRDNA genome-editing technology enables superior precision to develop cell therapies that are armored to potentially improve activity against diseases. Caribou is focused on vispacabtagene regedleucel (vispa-cel) and CB-011 as off-the-shelf CAR-T cell therapies that have the potential to provide broad access and rapid treatment for patients with hematologic malignancies. Follow the Company @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. 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, but are not limited to, any statements regarding the initiation, timing, progress, strategy, plans, objectives, expectations (including as to the results) with

respect to the Company's CAR-T cell therapy product candidate clinical trials, including its expectations regarding reporting dose expansion data, along with longer follow-up data on dose escalation, in 2026 from its ongoing CaMMouflage phase 1 clinical trial for CB-011 in patients with r/r MM; its expectations relating to discussions with the FDA regarding future clinical development of CB-011; its ability to successfully develop its CAR-T cell therapy product candidates and to obtain and maintain regulatory approval for these product candidates; the likelihood of its clinical trials demonstrating safety and efficacy of its CAR-T cell therapy product candidates; the beneficial characteristics, safety, efficacy, therapeutic effects, and potential advantages of its CAR-T cell therapy product candidates; and the expected timing or likelihood of regulatory filings and approval for its CAR-T cell therapy product candidates. 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 allogeneic CAR-T cell therapy products; uncertainties related to the initiation, cost, timing, progress, and results of its current and future clinical trials; the risk that initial, preliminary, or interim clinical trial data will not ultimately be predictive of the safety and efficacy of its CAR-T cell therapy product candidates or that clinical outcomes may differ as patient enrollment continues and as more patient data becomes available; the risk that different conclusions or considerations are reached once additional data have been received and fully evaluated; the ability to obtain key regulatory input and approvals; and risks related to its limited operating history, history of net operating losses, financial position, and its ability to raise additional capital as needed to fund its operations and CAR-T cell therapy product candidate development, including the ability to fully fund its pivotal phase 3 clinical trial for vispa-cel; as well as other risk factors described from time to time in Caribou's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2025, and subsequent SEC 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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