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): January 7, 2024

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 January 7, 2024, Caribou Biosciences, Inc. ("Caribou" or the "Company") issued a press release announcing the appointment of Tim Kelly as Chief Technology Officer of the Company, highlighting 2023 clinical events and corporate accomplishments, and providing an outlook of anticipated 2024 clinical milestones. A copy of the press release is furnished herewith as Exhibit 99.1 and also is incorporated by reference into this Item 7.01.

The information set forth under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Item 8.01 Other Events.

On January 7, 2024, the Company issued a press release announcing the appointment of Tim Kelly as Chief Technology Officer of the Company.

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 Caribou's strategy, plans, and objectives, and expectations regarding its clinical and preclinical development programs, including its expectations relating to the timing of status and updates from its ANTLER phase 1 clinical trial for CB-010, including expectations regarding the timing of reporting initial dose expansion data from the ANTLER trial and disclosure of the recommended phase 2 dose for CB-010, its planned phase 3 pivotal trial for CB-010 in second-line relapsed or refractory large B cell lymphoma patients, the status and updates from its CaMMouflage phase 1 clinical trial for CB-011 and expectations regarding the timing of reporting initial dose escalation data, expectations regarding the timing of initiating patient enrollment in the AMpLify phase 1 clinical trial for CB-012, and Caribou's expected cash runway. 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.

In addition, caution should be exercised when interpreting results from separate trials involving separate product candidates. Clinical trials of other companies' CAR-T cell therapies referenced in this press release were run independently of Caribou and Caribou has only reviewed publicly available reports of those trials. Caribou has not performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-010. As such, the results of these other clinical trials may not be comparable to clinical results for CB-010. The design of these other trials vary in material ways from the design of the clinical trials for CB-010, including with respect to patient populations, follow-up times, the clinical trial phase, and subject characteristics. As a result, cross-trial comparisons may have no interpretive value on Caribou's existing or future results. For further information and to understand these material differences, you should read the reports for the other companies' clinical trials.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Caribou Biosciences, Inc. on January 7, 2024
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: January 8, 2024

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Appoints Tim Kelly as Chief Technology Officer and Highlights Multiple Clinical Catalysts Expected in 2024

-- Tim Kelly to lead Caribou's technical operations strategy and execution --

-- CB-010 ANTLER Phase 1 trial initial dose expansion data and RP2D to be disclosed Q2 2024; Caribou plans to initiate pivotal Phase 3 trial in 2L LBCL by YE 2024 --

-- CB-011 CaMMouflage Phase 1 trial enrolling patients at dose level 3; initial dose escalation data in r/r MM expected by YE 2024 --

-- CB-012 AMpLify Phase 1 trial first sites active; trial initiation in r/r AML expected H1 2024 --

-- Caribou to present at 42nd Annual J.P. Morgan Healthcare Conference on Thursday, January 11, at 11:15 am PST --

BERKELEY, CA, January 7, 2024 – Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today announced the appointment of Tim Kelly to the newly created position of chief technology officer. Mr. Kelly brings over 25 years of experience in global clinical and commercial product development, manufacturing, and supply chain operations with large and small biopharmaceutical and cell and gene therapy companies in the US and Europe. In addition, Caribou highlighted successful execution across its allogeneic CAR-T cell therapy platform over the past year and provided an outlook on multiple clinical catalysts planned for 2024.

"2023 was a year of exceptional progress and leadership for Caribou as we advanced our three clinical programs and strengthened our balance sheet with a public offering and investment from Pfizer. We are excited to kick off 2024 by welcoming Tim Kelly as Caribou's chief technology officer," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "Tim's extensive experience in global pharmaceutical product development, manufacturing, and commercialization, combined with his proven leadership and strategic vision, will be instrumental as we advance our pipeline and plan for the future. We are pleased to have Tim join us on our mission of bringing transformative therapies to patients with devastating diseases."

Mr. Kelly will lead the company's technical operations strategy and execution and will report to Dr. Haurwitz. Tim joins Caribou from Oxford Biomedica Solutions, a spin-out of Homology Medicines, offering AAV product development and manufacturing services, where he was chief executive officer and board chair. Prior to Oxford Biomedica Solutions, he was chief operating officer at Homology Medicines, Inc., where he led operations, process and platform development strategy, and product manufacturing strategy for gene therapy and gene editing technology. Earlier, he led technical operations at Sarepta, Shire, UCB, and Biogen, and was a fighter pilot in the US Air Force. Tim earned an MS/MBA from Troy State University and a BS, with an emphasis in engineering mechanics, from the United States Air Force Academy.

"I'm thrilled to join Caribou as the company prepares to initiate its first pivotal trial. The potential of genome editing to revolutionize medicine is undeniable, and Caribou's innovative chRDNA technology has enabled development of armored allogeneic CAR-T cell therapies that hold immense

promise," said Mr. Kelly. "I look forward to leveraging my experience in building and scaling global process and manufacturing operations to ensure provider support and rapid patient access for commercialization and delivery of these potentially transformative therapies."

2023 clinical highlights and corporate accomplishments

Clinical highlights

CB-010, an allogeneic anti-CD19 CAR-T cell therapy for B cell non-Hodgkin lymphoma

- Caribou reported encouraging data (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-reports-positive-clinical-data-dose) from the dose escalation portion of the ANTLER Phase 1 trial (https://clinicaltrials.gov/study/NCT04637763) evaluating CB-010 in 16 patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). Dose escalation data showed CB-010's response rates and safety profile have the potential to rival those of the approved autologous CAR-T cell therapies.
- In the ongoing ANTLER Phase 1 trial, Caribou is enrolling second-line relapsed or refractory large B cell lymphoma (r/r LBCL) patients in the dose expansion portion. Currently, 22 U.S. and 3 international sites are active, with additional site activation underway.
- Caribou provided a regulatory update (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-provides-regulatory-update-cb-010-pivotal) based on feedback from the U.S. Food and Drug Administration (FDA) following a Type B clinical meeting. The company received the FDA's feedback on a Phase 3 randomized pivotal trial for CB-010 in second-line r/r LBCL stating that Caribou's proposed comparator arm of platinum-based immunochemotherapy followed by high dose chemotherapy (HDCT) and autologous stem cell transplantation (ASCT) is acceptable.
- 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 for specific indications.

"My enthusiasm for the potential of off-the-shelf cell therapies combined with the encouraging CB-010 dose escalation data prompted me to establish Westmead Hospital as the first international site for the ANTLER trial," said Kenneth Micklethwaite, MD, clinical associate professor at the University of Sydney and hematology staff specialist at the Westmead Hospital. "I look forward to participating in the planned pivotal trial as patients in the second-line setting have an urgent need for treatment given the limitations of current treatment options."

CB-011, an allogeneic anti-BMCA CAR-T cell therapy for multiple myeloma

- Caribou initiated (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-dosing-first-patient-cammouflage) the CaMMouflage Phase 1 trial evaluating CB-011 in patients with relapsed or refractory multiple myeloma (r/r MM).
- CB-011 was granted Fast Track (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-fda-granted-fast-track-designation) and Orphan Drug designation by the FDA, which are designed to expedite the development and review processes for promising therapeutic candidates that may fill an unmet medical need.
- CaMMouflage trial enrollment has concluded for dose level 1 ($50x10^6$ CAR-T cells, N=3) and dose level 2 ($150x10^6$ CAR-T cells, N=3) without any dose-limiting toxicities (DLTs), and the trial is enrolling patients at dose level 3 ($450x10^6$ CAR-T cells).

CB-012, an allogeneic anti-CLL-1 CAR-T cell therapy for acute myeloid leukemia

- The investigational new drug (IND) application for CB-012 was cleared by the FDA (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-fda-clearance-ind-application-cb-0) for evaluation in relapsed or refractory acute myeloid leukemia (r/r AML).
- The first clinical sites are active for the AMpLify Phase 1 trial (https://clinicaltrials.gov/study/NCT06128044?term=cb-012&rank=1&tab=table) for CB-012 in r/r AML with additional site activation underway.

Corporate accomplishments

Expanded executive leadership team (https://www.cariboubio.com/about/#leadership) and scientific advisory board (SAB) (https://www.cariboubio.com/about/#sab)

- Appointed Tim Kelly as Caribou's chief technology officer, leading the company's process development and manufacturing organizations.
- Appointed Reigin Zawadzki (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-appoints-reigin-zawadzki-chief-people) as Caribou's chief people officer, leading the company's people strategy.
- Expanded Caribou's SAB with a renowned lymphoma expert and two leading multiple myeloma experts:
    - Stephen Schuster, MD, (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-appointment-stephen-j-schuster-md) Robert and Margarita Louis-Dreyfus professor of chronic lymphocytic leukemia and lymphoma and the director of the lymphoma program and lymphoma translational research at the Perelman School of Medicine at the University of Pennsylvania, with Penn Medicine's Abramson Cancer Center.
    - Sundar Jagannath, MD, (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-appointment-sundar-jagannath-md) director of the Center of Excellence for Multiple Myeloma and professor of medicine at the Tisch Cancer Institute of Mount Sinai.
    - Sriram Krishnaswami, PhD, (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-25-million-equity-investment) vice president and development head for multiple myeloma at Pfizer Oncology's Global Product Development division.

Armored balance sheet for cash runway into Q4 2025

- Completed successful $134.4 million follow-on financing.
- Received $25 million Pfizer (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-25-million-equity-investment) investment with proceeds to advance CB-011.
- Reported $396.7 million in cash, cash equivalents, and marketable securities as of September 30, 2023, which is expected to fund the current operating plan into Q4 2025.

2024 anticipated milestones

CB-010: Caribou plans to report initial dose expansion data from the ANTLER trial and share the recommended Phase 2 dose (RP2D) for CB-010 in Q2 2024. The company plans to initiate a Phase 3 pivotal trial evaluating CB-010 in second-line LBCL by year-end 2024.

CB-011: Caribou plans to report initial dose escalation data by year-end 2024.
CB-012: Caribou plans to initiate patient enrollment in the AMpLify Phase 1 clinical trial in r/r AML in H1 2024.

Caribou to present at the 42nd Annual J.P. Morgan Healthcare Conference

Dr. Haurwitz is scheduled to present a corporate update at the 42nd Annual J.P. Morgan Healthcare Conference on Thursday, January 11, 2024 at 11:15 am PST.

A live webcast of the presentation will be accessible via Caribou's website on the Events (https://www.globenewswire.com/Tracker?data=ikVexELggjDIhnaJ9mXR11qhRxIE3k3rlPgn1oz-vydL2JgXbLTVtnnWah2yghFafQ_SyI9S8PHfxJWXDwlXhFp3KOj6r9OrftQgFgS8s-Q=) page. The archived webcast will be available on the Caribou website for 30 days after the event.

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. 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 for specific indications. Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov (https://clinicaltrials.gov/study/NCT04637763).

About CB-011

CB-011 is a 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 genome-editing technology. To Caribou's knowledge, CB-011 is the first allogeneic CAR-T cell therapy in the clinic 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. CB-011 has been granted Fast Track and orphan drug designations by the FDA. Additional information on the CaMMouflage trial (NCT05722418) can be found at clinicaltrials.gov (https://clinicaltrials.gov/study/NCT05722418).

About CB-012

CB-012 is a product candidate from Caribou's allogeneic CAR-T cell therapy platform and will be evaluated in the AMpLify Phase 1 clinical trial in patients with relapsed or refractory acute myeloid leukemia (r/r AML). CB-012 is an anti-CLL-1 CAR-T cell therapy engineered with five genome edits, enabled by Caribou's patented next-generation CRISPR technology platform, which uses Cas12a chRDNA genome editing to significantly improve the specificity of genome edits. To Caribou's knowledge, CB-012 is the first allogeneic CAR-T cell therapy with both checkpoint disruption, through a PD-1 knockout, and immune cloaking, through a B2M knockout and B2M–HLA-E fusion protein

insertion; both armoring strategies are designed to improve antitumor activity. Additional information on the AMpLify trial (NCT06128044) can be found at clinicaltrials.gov (https://clinicaltrials.gov/study/NCT06128044).

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 status and updates from its ANTLER Phase 1 clinical trial for CB-010, including expectations regarding the timing of reporting initial dose expansion data from the ANTLER trial and disclosure of the recommended Phase 2 dose for CB-010, its planned Phase 3 pivotal trial for CB-010 in second-line LBCL patients, as well as the status and updates from its CaMMouflage Phase 1 clinical trial for CB-011 and expectations regarding the timing of reporting initial dose escalation data, expectations about product developments, and expectations regarding the timing of initiating patient enrollment in the AMpLify Phase 1 clinical trial for CB-012, and Caribou's expected cash runway. 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.

In addition, caution should be exercised when interpreting results from separate trials involving separate product candidates. Clinical trials of other companies' CAR-T cell therapies referenced in this press release were run independently of Caribou and Caribou has only reviewed publicly available reports of those trials. Caribou has not performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-010. As such, the results of these other clinical trials may not be comparable to clinical results for CB-010. The design of these other trials vary in material ways from the design of the clinical trials for CB-010, including with respect to patient populations, follow-up times, the clinical trial phase, and subject characteristics. As a result, cross-trial comparisons may have no interpretive value on Caribou's existing or future results. For further information and to understand these material differences, you should read the reports for the other companies' clinical trials.

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