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): May 07, 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 2.02 Results of Operations and Financial Condition.

On May 7, 2024, Caribou Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing the Company's financial results for the quarter ended March 31, 2024 and providing a business update. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Reports First Quarter 2024 Financial Results and Provides Business Update

-- Advancing CB-010 ANTLER Phase 1 trial for 2L LBCL; initial dose expansion data to be presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting --

-- Expanding into autoimmune diseases with IND cleared for CB-010 in lupus nephritis and extrarenal lupus; GALLOP Phase 1 clinical trial expected to initiate by YE 2024 --

-- Advancing four clinical-stage programs for hematologic malignancies and autoimmune diseases; multiple milestones ahead --

-- $345.9 million in cash, cash equivalents, and marketable securities expected to fund the current operating plan into Q1 2026 --

BERKELEY, CA, May 7, 2024 (GLOBE NEWSWIRE) -- Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the first quarter 2024 and reviewed recent pipeline progress.

“We continue to focus on advancing four clinical-stage programs, including the parallel development of our lead allogeneic CAR-T cell therapy CB-010 in oncology and autoimmune diseases following our recent IND clearance in lupus,” said Rachel Haurwitz, PhD, Caribou’s president and chief executive officer. “Our clinical execution enables two clinical data readouts this year. At ASCO next month, we look forward to presenting initial dose expansion data for CB-010 in patients with second-line large B cell lymphoma. Additionally, by the end of this year we plan to present initial dose escalation data for CB-011 in relapsed or refractory multiple myeloma.”

Clinical highlights

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

- In the ongoing ANTLER Phase 1 trial, Caribou will enroll up to 20 additional patients with second-line large B cell lymphoma (LBCL) to prospectively evaluate partial human leukocyte antigen (HLA) matching. Based on an ongoing retrospective examination of ANTLER Phase 1 trial data, partial HLA matching may lead to improved clinical outcomes.

CB-010, a clinical-stage allogeneic anti-CD19 CAR-T cell therapy for lupus

- Caribou received clearance of an Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to evaluate CB-010 in the treatment of patients with lupus nephritis (LN) and extrarenal lupus (ERL).
- The GALLOP Phase 1 trial is an open-label, multicenter clinical trial designed to evaluate a single infusion of CB-010 in adult patients with LN and ERL. The trial will incorporate partial HLA matching between donor sources and patients.

CB-011, a clinical-stage allogeneic anti-BCMA CAR-T cell therapy for multiple myeloma

- Caribou is enrolling patients with relapsed or refractory multiple myeloma (r/r MM) in the dose escalation portion of the ongoing CaMMouflage Phase 1 clinical trial (https://clinicaltrials.gov/study/NCT05722418).

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

- Caribou is enrolling patients with relapsed or refractory acute myeloid leukemia (r/r AML) in the dose escalation portion of the ongoing AMpLify Phase 1 clinical trial (https://clinicaltrials.gov/study/NCT06128044?term=cb-012&rank=1&tab=table).

Upcoming medical meeting

2024 ASCO Annual Meeting, Chicago, IL

- **CB-010 ANTLER Phase 1 trial clinical data poster presentation:**
  A CRISPR-edited allogeneic anti-CD19 CAR-T cell therapy with a PD-1 knockout (CB-010) in patients with relapsed/refractory B cell non-Hodgkin lymphoma (r/r B-NHL): Updated Phase 1 results from the ANTLER trial
  Boyu Hu, MD, assistant professor, director of lymphoma and CLL, division of hematology/hematologic malignancies, Huntsman Cancer Institute at the University of Utah
  Monday, June 3, 2024, 9:00 am-12:00 pm CDT
- **CB-012 AMpLify Phase 1 trial design poster presentation:**
  A first-in-human Phase 1, multicenter, open-label study of CB-012, a next-generation CRISPR-edited allogeneic anti-CLL-1 CAR-T cell therapy for adults with relapsed/refractory acute myeloid leukemia (AMpLify)
  Naval Daver, MD, associate professor and director of the Leukemia Research Alliance Program, department of leukemia, The University of Texas MD Anderson Cancer Center
  Monday, June 3, 2024, 9:00 am-12:00 pm CDT

2024 anticipated milestones

- **CB-010 ANTLER:** At the 2024 ASCO Annual Meeting, Caribou plans to present a poster with data from the ongoing ANTLER Phase 1 trial data for CB-010. The update will include:
  - Initial safety and efficacy data on the first 30 patients enrolled in dose expansion
  - Updated safety and efficacy data on the 7 dose escalation patients who remained on study when the data were last reported
  - The recommended Phase 2 dose (RP2D)
  - Translational data (pharmacokinetics, pharmacodynamics, including B cell aplasia, and partial HLA matching)
  - Timelines for clinical data on up to 20 patients with partial HLA matching
- **CB-010 GALLOP:** Caribou plans to initiate the GALLOP Phase 1 clinical trial in adult patients with LN and ERL by year-end 2024.
- **CB-011 CaMMouflage:** Caribou plans to present initial dose escalation data from the ongoing CaMMouflage Phase 1 clinical trial by year-end 2024.
- **CB-012 AMpLify:** Caribou plans to provide updates on dose escalation as the AMpLify Phase 1 clinical trial in r/r AML advances.

First quarter 2024 financial results

Cash, cash equivalents, and marketable securities: Caribou had $345.9 million in cash, cash equivalents, and marketable securities as of March 31, 2024, compared to $372.4 million as of December 31, 2023. The March 31, 2024 balance includes approximately $11.3 million in net proceeds from the sale of Caribou's common stock under the Company's ATM Sales Agreement. Caribou expects these cash, cash equivalents, and marketable securities will be sufficient to fund its current operating plan into Q1 2026.

Licensing and collaboration revenue: Revenue from Caribou's licensing and collaboration agreements was $2.4 million for the three months ended March 31, 2024, compared to $3.5 million for the same period in 2023. The decrease primarily was due to the now-terminated AbbVie Collaboration and License Agreement as previously disclosed, partially offset by an increase in revenues recognized under the Information Rights Agreement Caribou entered into with Pfizer on June 29, 2023.
R&D expenses: Research and development expenses were $33.8 million for the three months ended March 31, 2024, compared to $25.7 million for the same period in 2023. The increase was primarily due to costs to advance pipeline programs, including the CB-010 ANTLER, CB-011 CaMMouflage, and CB-012 AMpLify Phase 1 clinical trials; personnel-related expenses, including stock-based compensation, due to headcount increases; and facilities and other allocated expenses.

G&A expenses: General and administrative expenses were $14.6 million for the three months ended March 31, 2024, compared to $8.9 million for the same period in 2023. The increase was primarily due to legal expenses and other service-related expenses, including accrued litigation settlement costs; personnel-related expenses, including stock-based compensation, due to headcount increases; and other facilities and allocated expenses. These increases were partially offset by a decrease in patent prosecution and maintenance fees.

Net loss: Caribou reported a net loss of $41.2 million for the three months ended March 31, 2024, compared to $28.0 million for the same period in 2023.

About CB-010

CB-010 is the lead clinical-stage product candidate from Caribou's allogeneic CAR-T cell therapy platform, and it is being evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL) in the ongoing ANTLER Phase 1 clinical trial and will be evaluated in patients with lupus nephritis (LN) and extrarenal lupus (ERL) in the GALLOP Phase 1 clinical trial. In ANTLER, 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). 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 activity against diseases by limiting premature CAR-T cell exhaustion. CB-010 is also, to Caribou's knowledge, the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting and, for r/r B-NHL, CB-010 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 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 is being 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. Caribou has exclusively in-licensed from Memorial Sloan Kettering Cancer Center (MSKCC) in the field of allogeneic CLL-1-targeted cell therapy a panel of fully human scFvs targeting CLL-1, from which the company has selected an appropriate scFv for the generation of the company's CAR. 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 chRDNA technology to carry out high efficiency multiple edits, 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 clinical-stage off-the-shelf cell therapies from its CAR-T cell platform as readily available treatments for patients with hematologic malignancies and autoimmune diseases. 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. 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 (i) the timing of reporting initial dose expansion data, translational data, follow-up dose escalation data from the ANTLER trial, disclosure of the recommended Phase 2 dose for CB-010, the possibility of improved clinical outcomes by utilizing partial human leukocyte antigen matching, and timelines for clinical data on partial HLA matching; (ii) the timing of status and updates from its CaMMouflage Phase 1 clinical trial for CB-011 and expectations regarding the timing of presenting the initial dose escalation data; (iii) the timing of status and updates from its AMpLify Phase 1 clinical trial for CB-012; (iv) the timing of status and updates from its GALLOP Phase 1 clinical trial for CB-010 in patients with LN and ERL; and (v) its expected funding runway of cash, cash equivalents, and marketable securities. 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, 2023 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.

Caribou Biosciences, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 345,926	$ 372,404
Total assets	406,825	432,209
Total liabilities	63,536	63,808
Total stockholders' equity	343,289	368,401
Total liabilities and stockholders' equity	$ 406,825	$ 432,209

Caribou Biosciences, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended, March 31,	
	2024	**2023**
Licensing and collaboration revenue	$ 2,429	$ 3,502
Operating expenses:		
Research and development	33,788	25,709
General and administrative	14,643	8,909
Total operating expenses	48,431	34,618
Loss from operations	(46,002)	(31,116)
Other income (expense):		
Change in fair value of equity securities	—	(15)
Change in fair value of the MSKCC success payments liability	303	255
Other income, net	4,465	2,832
Total other income	4,768	3,072
Net loss	$ (41,234)	$ (28,044)
Other comprehensive income (loss):		
Net unrealized (loss) gain on available-for-sale marketable securities, net of tax	(352)	788
Net comprehensive loss	$ (41,586)	$ (27,256)
Net loss per share, basic and diluted	$ (0.46)	$ (0.46)
Weighted-average common shares outstanding, basic and diluted	89,302,937	61,186,514

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