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 11, 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 March 11, 2024, Caribou Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing the Company's financial results for the fourth quarter and year ended December 31, 2023 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, 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 March 11, 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: March 11, 2024

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

-- 30th patient dosed in CB-010 ANTLER Phase 1 trial dose expansion; initial dose expansion data and RP2D to be disclosed in Q2 2024 --

-- 1st patient dosed in CB-012 AMpLify Phase 1 trial for patients with r/r AML --

-- $372.4 million in cash, cash equivalents, and marketable securities expected to fund the current operating plan into Q1 2026 --

BERKELEY, Calif., March 11, 2024 (GLOBE NEWSWIRE) -- Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the fourth quarter and full year 2023 and reviewed recent pipeline progress.

"Following our execution in 2023, we enter 2024 with momentum advancing three clinical-stage off-the-shelf CAR-T cell therapy programs for patients with hematologic malignancies while we plan for two clinical data releases this year," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "For our lead program, CB-010, we plan to present initial dose expansion data and the RP2D in the second quarter of 2024. For our second program, CB-011, we continue to enroll patients in the CaMMouflage trial and plan to report initial dose escalation data by year-end 2024. For our third program, CB-012, we are thrilled to have recently dosed the first patient in the AMpLify trial. Our team is focused on clinical execution to inform two clinical datasets this year as part of our mission of bringing transformative therapies to patients with devastating diseases."

Clinical highlights

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

- Caribou has dosed the 30th patient in the dose expansion portion of the ongoing ANTLER Phase 1 clinical trial (https://clinicaltrials.gov/study/NCT04637763) in second-line relapsed or refractory large B cell lymphoma (r/r LBCL) patients. Previously, 16 patients were dosed in the dose escalation portion of ANTLER. The company will continue enrolling additional second-line r/r LBCL patients in ANTLER to collect additional clinical data.
- In December 2023, Caribou shared regulatory feedback (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-provides-regulatory-update-cb-010-pivotal) from the U.S. Food and Drug Administration (FDA) following a Type B clinical meeting. The company received the FDA's input 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.
- As previously reported, CB-010 demonstrated 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 clinical trial (https://clinicaltrials.gov/study/NCT04637763) in 16 patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). Dose escalation data showed CB-010 has the potential to rival the efficacy and safety profile of approved autologous CAR-T cell therapies.

- 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 was granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations by the FDA for specific indications in 2022.

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). Patients are currently being enrolled at dose level 3 ($450x10^6$ CAR-T cells).
- Preclinical data for CB-011 were published in *Cancer Immunology Research* (https://aacrjournals.org/cancerimmunolres/article/doi/10.1158/2326-6066.CIR-23-0679/734160/High-specificity-CRISPR-mediated-genome) in February 2024. The manuscript is available on Caribou's website under Scientific Publications (https://www.cariboubio.com/technology/#pubs).

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

- The first patient has been dosed in the AMpLify Phase 1 clinical trial (https://clinicaltrials.gov/study/NCT06128044?term=cb-012&rank=1&tab=table), which is evaluating CB-012 in patients with relapsed or refractory acute myeloid leukemia (r/r AML). Additional site activation is underway.
- Preclinical data for CB-012 highlighting the investigational new drug (IND)-enabling studies will be presented as a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2024, held April 5-10, 2024 in San Diego.

CB-020, a preclinical allogeneic anti-ROR1 CAR-NK cell therapy

- As part of a regular portfolio prioritization process, Caribou has paused the development of CB-020, a preclinical allogeneic anti-ROR1 CAR-NK cell therapy. Caribou continues to develop its CAR-NK cell therapy platform as these therapies may have potential for the treatment of multiple diseases.

2024 anticipated milestones

- **CB-010:** In Q2 2024, Caribou plans to present initial dose expansion data, the recommended Phase 2 dose (RP2D), and emerging translational data from the ANTLER Phase 1 clinical trial, as well as an updated timeline for the pivotal Phase 3 trial initiation.
- **CB-011:** Caribou plans to present initial dose escalation data from the CaMMouflage Phase 1 clinical trial by year-end 2024.
- **CB-012**: Caribou plans to provide updates on dose escalation as the AMpLify Phase 1 clinical trial in r/r AML advances.

Fourth Quarter and Full Year 2022 Financial Results

Cash, cash equivalents, and marketable securities: Caribou had $372.4 million in cash, cash equivalents, and marketable securities as of December 31, 2023, compared to $317.0 million as of December 31, 2022. The 2023 amount includes the approximately $134.4 million in net proceeds from the Company's underwritten public offering in July and August 2023 and the $25.0 million equity investment (https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-25-million-equity-investment) in June 2023 from Pfizer. 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 $3.6 million for the three months ended December 31, 2023 and $34.5 million for the full year 2023, compared to $3.7 million and $13.9 million, respectively, for the same periods 2022. The increase for the year ended December 31, 2023 was primarily due to $24.8 million in revenue recognized under the now-terminated AbbVie Collaboration and License Agreement, including $20.8 million of deferred revenue recognized upon termination of this agreement as previously disclosed, which was the remaining deferred revenue balance from AbbVie's $30 million upfront payment in February 2021.
R&D expenses: Research and development expenses were $31.3 million for the three months ended December 31, 2023 and $112.1 million for full year 2023, compared to $25.7 million and $82.2 million respectively, for the same periods in 2022. The increase for the year ended December 31, 2023 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 $9.7 million for the three months ended December 31, 2023 and $38.5 million for the full year 2023, compared to $8.5 million and $38.0 million, respectively, for the same periods in 2022. The increase for the year ended December 31, 2023 was primarily due to personnel-related expenses, including stock-based compensation, due to headcount increases, and other facilities and allocated expenses. These increases were partially offset by decreases in insurance and other service-related expenses, and patent prosecution and maintenance costs.

Net loss: Caribou reported a net loss of $34.5 million for the three months ended December 31, 2023 and $102.1 million for the full year 2023, compared to a net loss of 27.0 million and $99.4 million, respectively, for the same periods in 2022.

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 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 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 clinical-stage off-the-shelf cell therapies from its CAR-T platform as readily available treatments for patients with hematologic malignancies. 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 (i) the timing of reporting initial dose expansion data, emerging translational data, follow-up dose escalation data from the ANTLER trial, disclosure of the recommended Phase 2 dose for CB-010, and updated timeline for its planned Phase 3 pivotal trial for CB-010 in second-line LBCL patients; (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; and (iv) its 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, 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.

In addition, caution should be exercised when interpreting results from separate trials of other companies' CAR-T cell therapies referenced in this press release. Caribou has not performed any head-to-head trials comparing any of these other CAR-T cell therapies with CB-010 and the design and patient populations of those other trials may vary in material ways from those of CB-010. As such, the results of these other clinical trials may not be comparable to clinical results for CB-010. Cross-trial comparisons may have no interpretive value on Caribou's existing or future results.

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 372,404	$ 317,036
Total assets	432,209	373,765
Total liabilities	63,808	72,894
Total stockholders' equity	368,401	300,871
Total liabilities and stockholders' equity	$ 432,209	$ 373,765

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Licensing and collaboration revenue	$ 3,558	$ 3,692	$ 34,477	$ 13,851
Operating expenses:				
Research and development	31,279	25,736	112,075	82,230
General and administrative	9,721	8,534	38,461	38,020
Total operating expenses	41,000	34,270	150,536	120,250
Loss from operations	(37,442)	(30,578)	(116,059)	(106,399)
Other income (expense):				
Change in fair value of equity securities	(9)	(60)	(6)	(133)
Change in fair value of the MSKCC success payments liability	(1,683)	1,388	(1,288)	2,429
Other income, net	4,822	2,331	15,476	4,752
Total other income (expense)	3,130	3,659	14,182	7,048
Net loss before provision for income taxes	$ (34,312)	$ (26,919)	$ (101,877)	$ (99,351)
Provision for income taxes	193	70	193	70
Net loss	$ (34,505)	$ (26,989)	$ (102,070)	$ (99,421)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale marketable securities	1,011	517	1,548	(1,383)
Net comprehensive loss	$ (33,494)	$ (26,472)	$ (100,522)	$ (100,804)
Net loss per share, basic and diluted	$ (0.39)	$ (0.44)	$ (1.38)	$ (1.64)
Weighted-average common shares outstanding, basic and diluted	88,432,905	61,001,150	73,807,597	60,801,133

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