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 09, 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 2.02 Results of Operations and Financial Condition.

On March 9, 2023, 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, 2022 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 9, 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: March 9, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer

Caribou Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

-- CB-010 ANTLER Phase 1 trial in r/r B-NHL ongoing with update planned for H2 2023 --

-- CB-011 CaMMouflage Phase 1 trial in r/r MM recruiting patients at dose level 1 --

-- CB-012 IND-enabling studies initiated; IND submission in r/r AML planned for H2 2023 --

-- $317.0 million in cash, cash equivalents, and marketable securities as of December 31, 2022; cash runway to fund the current operating plan into 2025 --

BERKELEY, CA, March 9, 2023 – 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 2022 and reviewed recent pipeline progress.

“We successfully demonstrated the potential of our chRDNA genome-editing technology with promising clinical data from CB-010, our lead allogeneic cell therapy,” said Rachel Haurwitz, PhD, Caribou’s president and chief executive officer. “The initial dose level of CB-010 demonstrated 6-month complete response rates that have the potential to rival the responses seen with approved autologous CAR-T cell therapies. We are excited that the FDA granted the CB-010 program RMAT and Fast Track designations last year. Our team drove additional pipeline progress with an IND clearance for CB-011, enabling us to activate clinical sites for our CaMMouflage Phase 1 trial. In 2023, Caribou plans to maintain this momentum by advancing two ongoing clinical trials for our off-the-shelf cell therapies in patients with hematologic malignancies and preparing an IND submission for our third program, CB-012.”

Accomplishments and Highlights

Pipeline and Technology

- **CB-010**: Caribou reported promising data at dose level 1 ($40x10^6$ CAR-T cells) from its ongoing ANTLER Phase 1 clinical trial of CB-010 in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL).
  - Following a single infusion of CB-010 at dose level 1, all 6 patients in cohort 1 achieved complete responses as their best response. 3 of 6 patients maintained complete responses at 6 months, with 2 of 6 maintaining complete responses at 12 months. Caribou plans to provide an update from the ongoing ANTLER Phase 1 trial for CB-010 in H2 2023.
  - Clinical data presentations are available on Caribou’s website under Scientific Publications (www.cariboubio.com/technology/#pubs).
  - Following demonstration of an encouraging safety profile at dose level 2 ($80x10^6$ CAR-T cells), with no dose-limiting toxicities (DLTs) in the 3 patients treated, Caribou continues to enroll patients at dose level 3 ($120x10^6$ CAR-T cells).
  - The U.S. Food and Drug Administration (FDA) has granted CB-010 Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations. These

designations provide important benefits in the drug development process and are 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.
    - CB-010 is the first allogeneic anti-CD19 CAR-T cell therapy in the clinic, to Caribou's knowledge, with a PD-1 knockout (KO), a genome-editing strategy designed to improve antitumor activity by limiting premature CAR-T cell exhaustion.
    - Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT04637763).
- **CB-011**: Caribou recently activated clinical sites for the recruitment of patients at dose level 1 ($50x10^6$ CAR-T cells) of CB-011 in the CaMMouflage Phase 1 trial for relapsed or refractory multiple myeloma (r/r MM).
    - 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* KO and insertion of a B2M–HLA-E fusion protein to blunt immune-mediated rejection.
    - Preclinical data for CB-011 were presented in a poster at the 2023 Tandem Meeting: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, February 15-19, 2023, in Orlando, Florida. The poster presentation is available on Caribou's website under Scientific Publications (www.cariboubio.com/technology/#pubs).
    - Additional information on the CaMMouflage trial (NCT05722418) can be found at clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT05722418).
- **CB-012:** Caribou has initiated IND-enabling studies for CB-012, an allogeneic anti-CLL-1 CAR-T cell therapy, to support a planned IND application submission for relapsed or refractory acute myeloid leukemia (r/r AML).
    - CB-012 is the first allogeneic CAR-T cell therapy, to Caribou's knowledge, with both checkpoint disruption, through a PD-1 KO, and immune cloaking, through a *B2M* KO and B2M–HLA-E fusion protein insertion; both armoring strategies are designed to improve antitumor activity. CB-012 is engineered with 5 genome edits, enabled by Caribou's next-generation CRISPR technology platform, which uses Cas12a chRDNA genome editing to significantly improve the specificity of genome edits.
    - In preclinical AML models, CB-012 significantly reduced tumor burden and increased overall survival compared to controls.
- **CB-020:** Caribou's first induced pluripotent stem cell (iPSC)-derived allogeneic CAR-NK cell therapy, CB-020, is designed to target solid tumors expressing the tumor antigen ROR1.
    - Preclinical data supporting the selection of the ROR1 CAR construct and armoring strategies for the company's CAR-NK cell platform were presented at the 12th American Association for Cancer Research and Japanese Cancer Association (AACR-JCA) Joint Conference in December 2022. The poster presentation is available on Caribou's website under Scientific Publications (www.cariboubio.com/technology/#pubs).

Anticipated 2023 Milestones

- **CB-010:** Caribou plans to provide an update from the ongoing ANTLER Phase 1 trial for CB-010 in H2 2023.

- **CB-011:** Caribou recently activated clinical sites for the recruitment of patients at dose level 1 and plans to provide an update on the clearance of dose levels as appropriate from the CaMMouflage Phase 1 trial for CB-011.
- **CB-012**: Caribou plans to submit an IND application for CB-012 in H2 2023.

Upcoming Investor Conferences

- Caribou management plans to participate in the following investor conferences:
  - March 15: Oppenheimer's 33rd Annual Healthcare Investor Conference, virtual
  - May 9-11: BofA Securities 2023 Healthcare Conference, Las Vegas

Fourth Quarter and Full Year 2022 Financial Results

Cash, cash equivalents, and marketable securities: Caribou had $317.0 million in cash, cash equivalents, and marketable securities as of December 31, 2022, compared to $413.5 million as of December 31, 2021. Caribou expects these cash, cash equivalents, and marketable securities will be sufficient to fund its current operating plan into 2025.

Licensing and collaboration revenue: Revenue from Caribou's licensing and collaboration agreements was $3.7 million for the three months ended December 31, 2022 and $13.9 million for the full year 2022, compared to $2.6 and $9.6 million, respectively, for the same periods 2021. The increases were primarily due to revenue recognized under the AbbVie Agreement.
R&D expenses: Research and development expenses were $25.7 million for the three months ended December 31, 2022 and $82.2 million for full year 2022, compared to $15.1 and $52.3 million respectively, for the same periods in 2021. The increases were primarily due to costs to advance pipeline programs; increased headcount, including stock-based compensation; facilities and other allocated expenses; and increased external manufacturing and clinical activities.

G&A expenses: General and administrative expenses were $8.5 million for the three months ended December 31, 2022 and $38.0 million for the full year 2022, compared to $7.9 and $24.3 million, respectively, for the same periods in 2021. The increases were primarily due to increased headcount, including stock-based compensation; legal, accounting, insurance, and other expenses necessary to support the growth and operation of a clinical-stage public company; and facilities and other allocated expenses.

Net loss: Caribou reported a net loss of $27.0 million for the three months ended December 31, 2022 and $99.4 million for the full year 2022, compared to a net loss of $18.5 and $66.9 million, respectively, for the same periods in 2021.

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 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 timing of updates from its ANTLER Phase 1 clinical trial for CB-010 as well as the status and updates from its CaMMouflage Phase 1 clinical trial for CB-011, expectations about product developments in 2023, and the submission of an IND application for CB-012. 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.

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 317,036	$ 413,508
Total assets	373,765	442,356
Total liabilities	72,894	54,531
Total stockholders' equity	300,871	387,825
Total liabilities and stockholders' equity	$ 373,765	$ 442,356

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,	
	2022	2021	2022	2021
Licensing and collaboration revenue	$ 3,692	$ 2,559	$ 13,851	$ 9,598
Operating expenses:				
Research and development	25,736	15,111	82,230	52,255
General and administrative	8,534	7,853	38,020	24,322
Total operating expenses	34,270	22,964	120,250	76,577
Loss from operations	(30,578)	(20,405)	(106,399)	(66,979)
Other income (expense):				
Change in fair value of equity securities	(60)	—	(133)	—
Change in fair value of the MSKCC success payments liability	1,388	2,158	2,429	(1,426)
Gain on extinguishment of PPP Loan	—	—	—	1,584
Other income, net	2,331	89	4,752	219
Total other income (expense)	3,659	2,247	7,048	377
Net loss before provision for income taxes	$ (26,919)	$ (18,158)	$ (99,351)	$ (66,602)
Provision for income taxes	70	321	70	321
Net loss	$ (26,989)	$ (18,479)	$ (99,421)	$ (66,923)
Other comprehensive loss:				
Net unrealized loss on available-for-sale marketable securities	517	(135)	(1,383)	(135)
Net comprehensive loss	$ (26,472)	$ (18,614)	$ (100,804)	$ (67,058)
Net loss per share, basic and diluted	$ (0.44)	$ (0.31)	$ (1.64)	$ (2.11)
Weighted-average common shares outstanding, basic and diluted	61,001,150	60,180,759	60,801,133	31,663,243

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