
**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): November 07, 2023

Caribou Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40631
(Commission File Number)

45-3728228
(IRS Employer
Identification No.)

2929 7th Street, Suite 105
Berkeley, California
(Address of Principal Executive Offices)

94710
(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 November 7, 2023, Caribou Biosciences, Inc., a Delaware corporation (the “Company”), issued a press release announcing the Company’s financial results for the quarter ended September 30, 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, 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 November 7, 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: November 7, 2023

By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz
President and Chief Executive Officer



Caribou Biosciences Reports Third Quarter 2023 Financial Results and Provides Business Update

-- CB-010 ANTLER Phase 1 trial continues enrolling second-line r/r LBCL patients in dose expansion; plan to share FDA feedback by year-end 2023 and report initial dose expansion data in H1 2024 --

-- CB-011 CaMMouflage Phase 1 trial enrollment ongoing in r/r MM patients --

-- CB-012 AMpLify Phase 1 trial site activation underway following recent IND clearance; expect to initiate enrollment by mid-2024 in r/r AML patients --

-- \$396.7 million in cash, cash equivalents, and marketable securities expected to fund the current operating plan into Q4 2025 --

BERKELEY, CA, November 7, 2023 – Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the third quarter of 2023 and reviewed recent business updates.

“In 2023, we have advanced our programs to build value across the pipeline and position Caribou as a leader in the allogeneic CAR-T cell therapy space,” said Rachel Haurwitz, PhD, Caribou’s president and chief executive officer. “We plan to meet with the FDA to discuss a potential pivotal trial in second-line LBCL patients for our lead program, CB-010, and we intend to share the agency’s feedback by the end of this year. Patient enrollment is ongoing in the ANTLER trial, and we expect to report initial dose expansion data in the first half of 2024. Additionally, we are enrolling patients in our CaMMouflage trial for CB-011 and plan to initiate enrollment in the AMpLify Phase 1 clinical trial for CB-012 by mid-2024. With two years of cash and continued financial discipline, we are well positioned to execute on our current programs and continue Caribou’s momentum.”

Accomplishments and highlights

Pipeline and technology

- **CB-010:** Caribou continues to enroll second-line LBCL patients in the dose expansion portion of the ongoing ANTLER Phase 1 clinical trial based on positive data from the dose escalation portion of the trial. CB-010 is an allogeneic anti-CD19 CAR-T cell therapy in development for relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). The dose expansion data will be used to determine the recommended Phase 2 dose (RP2D).
- **CB-011:** Caribou continues to enroll patients at dose level 2 (150×10^6 CAR-T cells) in the dose escalation portion of the ongoing CaMMouflage Phase 1 trial of CB-011, an allogeneic anti-BCMA CAR-T cell therapy, for relapsed or refractory multiple myeloma (r/r MM). Caribou has concluded dose level 1 (50×10^6 CAR-T cells, N=3) without any dose-limiting toxicities (DLTs) and received Study Steering Committee clearance to proceed with dosing patients at dose level 2.
- **CB-012:** Caribou recently announced clearance of the company’s investigational new drug (IND) application from the U.S. Food and Drug Administration (FDA) for CB-012, an allogeneic anti-CLL-1 CAR-T cell therapy, for relapsed or refractory acute myeloid leukemia (r/r AML). Clinical site activation is underway for the AMpLify Phase 1 clinical trial and Caribou plans to

initiate patient enrollment by mid-2024 to evaluate CB-012 at ascending dose levels starting at dose level 1 (25x10⁶ CAR-T cells).

Anticipated milestones

- **CB-010:** Caribou plans to meet with the FDA to discuss a potential pivotal clinical trial in second-line LBCL patients and plans to share FDA feedback by year-end 2023. The Company also plans to report initial dose expansion data in second-line LBCL patients from the ongoing ANTLER trial in H1 2024.
- **CB-011:** Caribou plans to provide updates on dose escalation as the CaMMouflage Phase 1 clinical trial in r/r MM advances.
- **CB-012:** Caribou plans to initiate patient enrollment in the AMpLify Phase 1 clinical trial in r/r AML by mid-2024.

Corporate updates

- **Appointed two multiple myeloma experts to Caribou's scientific advisory board:** Caribou appointed two experts in multiple myeloma drug development to its scientific advisory board [www.cariboubio.com/about/#sab] in the third quarter of 2023.
 - 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, vice president and development head for multiple myeloma at Pfizer Oncology's Global Product Development division.
- **Appointed chief people officer:** In September 2023, Caribou appointed Reigin Zawadzki [<https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-appoints-reigin-zawadzki-chief-people>] to the newly created position of chief people officer. Ms. Zawadzki brings over 20 years of experience leading human resources in the biotechnology industry and will lead Caribou's people strategy.
- **Completed successful \$134.4 million follow-on financing:** In the third quarter of 2023, Caribou completed an underwritten public offering of 22,115,384 shares of its common stock, which included the full exercise of the underwriters' option to purchase additional shares. The net proceeds to Caribou were \$134.4 million.
- **Received \$25.0 million Pfizer investment:** In July 2023, Caribou announced that Pfizer invested [<https://investor.cariboubio.com/news-releases/news-release-details/caribou-biosciences-announces-25-million-equity-investment>] \$25.0 million in Caribou common shares on June 30, 2023. Caribou will use the proceeds from this investment to advance CB-011. Caribou maintains full ownership and control of CB-011 and its other allogeneic CAR-T and CAR-NK cell therapies.

Third quarter 2023 financial results

Cash, cash equivalents, and marketable securities: Caribou had \$396.7 million in cash, cash equivalents, and marketable securities as of September 30, 2023, compared to \$317.0 million as of December 31, 2022. This amount includes the approximately \$134.4 million in net proceeds from the Company's underwritten public offering and the \$25.0 million equity investment from Pfizer. Caribou expects its cash, cash equivalents, and marketable securities will be sufficient to fund its current operating plan into Q4 2025.

Licensing and collaboration revenue: Revenue from Caribou's licensing and collaboration agreements was \$23.7 million for the three months ended September 30, 2023, compared to \$3.3



million for the same period 2022. The increase was primarily due to \$21.5 million in revenue recognized under the AbbVie Collaboration and License Agreement, including \$20.8 million of 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 \$28.6 million for the three months ended September 30, 2023, compared to \$20.0 million for the same period in 2022. The increase was primarily due to costs to advance pipeline programs, including the CB-010 ANTLER and CB-011 CaMMouflage 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 September 30, 2023, compared to \$9.8 million for the same period in 2022. The decrease was primarily due to lower patent prosecution and maintenance costs, and lower insurance, accounting, and other service-related expenses. This decrease was partially offset by an increase in personnel-related expenses, including stock-based compensation, due to headcount increases.

Net loss: Caribou reported a net loss of \$10.0 million for the three months ended September 30, 2023, compared to \$26.6 million for the same period 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, HGCL, 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. Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov.

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 designation by the FDA. Additional information on the CaMMouflage trial (NCT05722418) can be found at clinicaltrials.gov.

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.

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 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, plans for meeting with the FDA to discuss a potential pivotal clinical trial of CB-010 in second-line LBCL patients and plans for sharing feedback from such meeting, 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; 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)

	September 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	\$ 396,707	\$ 317,036
Total assets	457,521	373,765
Total liabilities	59,253	72,894
Total stockholders' equity	398,268	300,871
Total liabilities and stockholders' equity	\$ 457,521	\$ 373,765



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Licensing and collaboration revenue (\$622 and \$1,772 from related party for three and nine months ended September 2023, respectively)	\$ 23,662	\$ 3,303	\$ 30,919	\$ 10,159
Operating expenses:				
Research and development	28,584	19,991	80,796	56,494
General and administrative	9,711	9,849	28,740	29,486
Total operating expenses	38,295	29,840	109,536	85,980
Loss from operations	(14,633)	(26,537)	(78,617)	(75,821)
Other income (expense):				
Change in fair value of equity securities	(4)	31	3	(73)
Change in fair value of the MSKCC success payments liability	(139)	(1,607)	395	1,041
Other income, net	4,774	1,466	10,654	2,421
Total other income (expense)	4,631	(110)	11,052	3,389
Net loss	\$ (10,002)	\$ (26,647)	\$ (67,565)	\$ (72,432)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale marketable securities, net of tax	155	(454)	537	(1,900)
Net comprehensive loss	\$ (9,847)	\$ (27,101)	\$ (67,028)	\$ (74,332)
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.44)	\$ (0.98)	\$ (1.19)
Weighted-average common shares outstanding, basic and diluted	83,783,992	60,886,921	68,878,921	60,731,520



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