# **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

	_	FORM 8-K	_
	_	CURRENT REPORT	_
	Pursuant to Secti	on 13 or 15(d) of the Securities Exch	ange Act of 1934
	Date of Repo	ort (Date of earliest event reported): Novemb	per 08, 2022
		Tibou Biosciences, I (Exact name of Registrant as Specified in Its Charter)	nc.
	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 T	Telephone Number, Including Area Code: (5	10) 982-6030
	(Form	N/A er Name or Former Address, if Changed Since Last Re	port)
	ck the appropriate box below if the Form 8-K filing provisions:	s is intended to simultaneously satisfy the filing	g obligation of the registrant under any of the
	Written communications pursuant to Rule 425 u	nder the Securities Act (17 CFR 230.425)	
	Soliciting material pursuant to Rule 14a-12 under	er the Exchange Act (17 CFR 240.14a-12)	
	Pre-commencement communications pursuant to	o Rule 14d-2(b) under the Exchange Act (17 Cl	FR 240.14d-2(b))
	Pre-commencement communications pursuant to	o Rule 13e-4(c) under the Exchange Act (17 CF	FR 240.13e-4(c))
	Securit	ies registered pursuant to Section 12(b) of th	ne 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
	cate by check mark whether the registrant is an emoter) or Rule 12b-2 of the Securities Exchange Act		of the Securities Act of 1933 (§ 230.405 of this
Eme	erging growth company ⊠		
	n emerging growth company, indicate by check mar evised financial accounting standards provided purs		ended transition period for complying with any new

#### Item 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Caribou Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing the Company's financial results for the quarter ended September 30, 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 November 8, 2022
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 8, 2022 By: /s/ Rachel E. Haurwitz

Rachel E. Haurwitz

President and Chief Executive Officer



### Caribou Biosciences Reports Third Quarter 2022 Financial Results and Provides Business Update

- -- CB-010 ANTLER Phase 1 trial in r/r B-NHL advancing; additional data from cohort 1 expected by YE 2022 --
  - -- CB-011 IND application for r/r MM submitted to FDA in Q4 2022 --
- -- Strong financial position of \$342.6 million in cash, cash equivalents, and marketable securities as of September 30, 2022 --

BERKELEY, CA, November 8, 2022 – Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the third quarter of 2022 and provided a business update.

"We have seen highly promising results from our lead allogeneic cell therapy, CB-010, at the lowest starting dose in the ANTLER clinical trial in patients with relapsed or refractory B cell non-Hodgkin lymphoma," said Rachel Haurwitz, Ph.D., Caribou's president and chief executive officer. "The safety and antitumor activity for CB-010 at dose level 1 are encouraging, and we look forward to generating additional efficacy and durability data from the dose escalation phase of the ANTLER trial. In addition, progress continues across our pipeline as we submitted our second IND, for CB-011, in the fourth quarter and plan to submit our third IND, for CB-012, in 2023. Later this year, we look forward to sharing the target selection for CB-020, the lead program in our CAR-NK platform for solid tumors."

## **Recent Business Highlights**

#### **Pipeline and Technology**

- For CB-011, an investigational new drug (IND) application was submitted to the U.S. Food and Drug Administration (FDA) in Q4 2022 for relapsed or refractory multiple myeloma (r/r MM).
- CB-010 and the ANTLER Phase 1 trial:
  - In October 2022, a poster for a case report on long-term follow up for the first patient dosed in the ANTLER Phase 1 trial was presented at the Lymphoma, Leukemia, & Myeloma (LL&M) Congress. This patient achieved a complete response (CR) at day 28 and maintained a long-term CR at 15 months following a single dose of CB-010 at dose level 1 (40x10° CAR-T cells). Before joining the ANTLER trial, the patient had received eight prior lines of systemic anti-cancer therapy for relapsed aggressive B cell non-Hodgkin lymphoma (r/r B-NHL).
  - Based on the promising initial safety data and response rates at dose level 1, the ANTLER trial is currently enrolling patients at dose level 2 (80x10° CAR-T cells).
  - In September 2022, CB-010 was granted Orphan Drug Designation (ODD) for follicular lymphoma (FL) by the FDA. Patients with aggressively behaving FL are 1 of 7 subtypes of r/r B-NHL patients eligible for enrollment in the dose escalation portion of the ANTLER Phase 1 trial.
  - As previously reported:
    - 6 of 6 patients (100%) achieved a CR as their best response
    - 3 of 6 patients (50%) maintained a CR at 6 months



- 15 months has been the longest CR, achieved by the first patient dosed with CB-010
- CB-010 at dose level 1 was generally well tolerated in the ANTLER trial

# **Anticipated Milestones for Fourth Quarter 2022 and Beyond**

- CB-010: Caribou plans to share additional data from cohort 1 of the ongoing ANTLER Phase 1 trial for CB-010, an allogeneic anti-CD19 CAR-T cell therapy for r/r B-NHL, by YE 2022.
- CB-011: Caribou anticipates the FDA's response to Caribou's IND application for CB-011, an allogeneic anti-BCMA CAR-T cell therapy for r/r MM, by YE 2022.
- CB-020: Caribou expects to announce target selection for CB-020, an iPSC-derived CAR-NK cell therapy for solid tumors, in Q4 2022. Additionally, Caribou expects to disclose armoring strategies under development for its CAR-NK cell platform in Q4 2022.
- CB-012: Caribou expects to submit an IND application for CB-012, an allogeneic anti-CLL-1 CAR-T cell
  therapy for relapsed or refractory acute myeloid leukemia (r/r AML), in 2023.

#### **Upcoming Meetings**

- American Society of Hematology (ASH) 64th Annual Meeting, December 10-13, 2022
  - Trial-in-progress poster presentation for the ANTLER Phase 1 trial of CB-010 in r/r B-NHL
  - Caribou management plans to participate in the following upcoming investor conferences:
    - November 14: Barclays 2022 Gene Editing & Gene Therapy Summit
    - November 17: Jefferies Global Healthcare Conference
    - November 30: 5th Annual Evercore ISI HealthCONx Conference
    - December 7: BofA Securities Biotech SMID Cap Conference

#### **Third Quarter 2022 Financial Results**

Cash, cash equivalents, and marketable securities: Caribou had \$342.6 million in cash, cash equivalents, and marketable securities as of September 30, 2022, compared to \$413.5 million as of December 31, 2021.

**Licensing and collaboration revenue:** Revenue from Caribou's licensing and collaboration agreements was \$3.3 million for the three months ended September 30, 2022, compared to \$4.0 million for the same period in 2021. The decrease was primarily due to a decrease in revenue under the AbbVie collaboration and license agreement.

**R&D expenses:** Research and development expenses were \$20.0 million for the three months ended September 30, 2022, compared to \$15.8 million for the same period in 2021. The increase was primarily due to costs to advance pipeline programs; increased headcount, including stock-based compensation; and facilities and other expenses; partially offset by a decrease related to the timing of external manufacturing activities.

**G&A expenses:** General and administrative expenses were \$9.8 million for the three months ended September 30, 2022, compared to \$6.8 million for the same period in 2021. The increase was



primarily due to costs for increased headcount, including stock-based compensation; facilities and other expenses; and legal, accounting, insurance, and other expenses necessary to support the growth and operation of a clinical-stage public company.

**Net loss:** Caribou reported a net loss of \$26.6 million for the three months ended September 30, 2022, compared to a net loss of \$21.0 million for the same period 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 specifically engineered for enhanced persistence. Caribou is advancing a pipeline of off-the-shelf CAR-T and CAR-NK cell therapies for the treatment of patients with hematologic malignancies and solid tumors.

For more information about Caribou, visit www.cariboubio.com and follow the company @CaribouBio.

"Caribou Biosciences" and the Caribou logo are registered trademarks of Caribou Biosciences, Inc.

#### **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 timing and expectations relating to the release of patient data from its ongoing ANTLER Phase 1 clinical trial for CB-010, the expectations regarding IND applications for CB-011 and CB-012, and target selection for CB-020. 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 related to our limited operating history, history of net operating losses, financial position and our ability to raise additional capital as needed to fund our operations and product candidate development; risks inherent in development of cell therapy products; uncertainties related to the initiation, cost, timing, progress, and results of 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; risks related to our ability to obtain and maintain regulatory approval for our product candidates; 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, 2021, 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, 2022			December 31, 2021		
Cash, cash equivalents, and marketable securities	\$	342,590	\$	413,508		
Total assets		398,823		442,356		
Total liabilities		74,709		54,531		
Total stockholders' equity		324,114		387,825		
Total liabilities and stockholders' equity	\$	398,823	\$	442,356		



# 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,				
		2022	2021		2022		2021
Licensing and collaboration revenue	\$	3,303	\$ 3,977	\$	10,159	\$	7,039
Operating expenses:							
Research and development		19,991	15,833		56,494		37,144
General and administrative		9,849	6,760		29,486		16,469
Total operating expenses		29,840	22,593		85,980		53,613
Loss from operations		(26,537)	(18,616)		(75,821)		(46,574)
Other income (expense):							
Change in fair value of equity securities		31	_		(73)		_
Change in fair value of the MSKCC success payments liability		(1,607)	(2,403)		1,041		(3,584)
Gain on extinguishment of PPP Loan		_	_		_		1,584
Other income, net		1,466	45		2,421		130
Total other income (expense)		(110)	 (2,358)		3,389		(1,870)
Net loss	\$	(26,647)	\$ (20,974)	\$	(72,432)	\$	(48,444)
Other comprehensive loss:			_		_		_
Net unrealized loss on available-for-sale marketable securities, net of tax		(454)	_		(1,900)		_
Net comprehensive loss	\$	(27,101)	\$ (20,974)	\$	(74,332)	\$	(48,444)
Net loss per share, basic and diluted	\$	(0.44)	\$ (0.46)	\$	(1.19)	\$	(2.20)
Weighted-average common shares outstanding, basic and diluted		60,886,921	45,889,646		60,731,520		22,052,944



# **Caribou Biosciences, Inc. Contacts:**

### Investors:

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#### Media:

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#### **Investors and Media:**

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