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

May 9, 2023

-- CB-010 ANTLER Phase 1 trial enrolling second-line LBCL patients in dose expansion; plan to report dose escalation data in H2 2023 --

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

-- CB-012 IND application for r/r AML planned for H2 2023 --

-- $291.0 million in cash, cash equivalents, and marketable securities as of March 31, 2023; cash runway to fund the current operating plan into 2025 --

BERKELEY, Calif., May 09, 2023 (GLOBE NEWSWIRE) -- Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the first quarter of 2023 and reviewed recent pipeline progress.

"We are driving important progress this year across our pipeline of allogeneic CAR-T cell therapies," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "Notably, we are advancing the ongoing ANTLER trial for our lead program CB-010, the first allogeneic cell therapy to be evaluated clinically in the second-line LBCL setting. Our goal is to provide access to a greater number of patients and potentially improve outcomes earlier in the disease course. Additionally, we are excited that the FDA granted CB-011 Fast Track designation for the treatment of relapsed or refractory multiple myeloma and that we have initiated patient dosing in our CaMMouflage trial. The momentum continues as we prepare CB-012, our third CAR-T cell program, for an IND application submission for relapsed or refractory acute myeloid leukemia in the second half of this year."

Accomplishments and Highlights

Pipeline and Technology

- **CB-010**: Caribou successfully completed dose escalation and has entered the dose expansion portion of the ongoing ANTLER Phase 1 clinical trial of CB-010 in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL).
  - Caribou currently is enrolling second-line patients with large B cell lymphoma (LBCL) in the dose expansion portion of the ANTLER trial in which two different CB-010 dose levels ($80x10^6$ CAR-T cells and $120x10^6$ CAR-T cells) are being evaluated, each as a single-dose regimen, in approximately 30 second-line patients (approximately 15 patients per dose level) to determine the recommended Phase 2 dose (RP2D). Once the RP2D is determined, Caribou may enroll additional patients in the ANTLER trial.
  - The FDA has granted CB-010 Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations.
- **CB-011**: Caribou has initiated patient dosing at dose level 1 ($50x10^6$ CAR-T cells) in the CaMMouflage Phase 1 trial for relapsed or refractory multiple myeloma (r/r MM).
  - The FDA recently granted CB-011 Fast Track designation for r/r MM.
- **CB-012:** Caribou is advancing IND-enabling activities 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).
  - Data presented at the American Association for Cancer Research (AACR) 2023 Annual Meeting demonstrated in preclinical AML models that CB-012 significantly reduced tumor burden and increased overall survival compared to controls.

Anticipated 2023 Milestones

- **CB-010:** Caribou plans to provide a safety and efficacy update in H2 2023 from the ongoing ANTLER Phase 1 clinical trial in r/r B-NHL, including data from at least 15 patients from dose escalation with a minimum of six months follow up.
- **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 submit an IND application for r/r AML in H2 2023.

First Quarter 2023 Financial Results

Cash, cash equivalents, and marketable securities: Caribou had $291.0 million in cash, cash equivalents, and marketable securities as of March 31, 2023, compared to $317.0 million as of December 31, 2022. Caribou expects its 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 $3.5 million for the three months ended March 31, 2023, compared to $2.7 million for the same period in 2022. The increase was primarily due to revenue recognized under the Collaboration and License Agreement with AbbVie and other license agreements.

R&D expenses: Research and development expenses were $25.7 million for the three months ended March 31, 2023, compared to $13.9 million for the same period in 2022. The increase was primarily due to costs to advance pipeline programs, including the ANTLER and CaMMouflage Phase 1 trials; increased personnel-related expenses, including stock-based compensation; and facilities and other allocated expenses.

G&A expenses: General and administrative expenses were $8.9 million for the three months ended March 31, 2023, compared to $9.6 million for the

same period in 2022. The decrease was primarily due to lower director and officer insurance, legal, and patent prosecution and maintenance costs. This decrease was partially offset by increased personnel-related expenses due to increased headcount.

Net loss: Caribou reported a net loss of $28.0 million for the three months ended March 31, 2023, compared to $19.1 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) comprising four different subtypes of aggressive r/r B-NHL (DLBCL NOS, PMBCL, HGBL, and tFL). CB-010 is an allogeneic anti-CD19 CAR-T cell therapy engineered using Cas9 CRISPR hybrid RNA-DNA (chRDNA) technology. CB-010 is the first allogeneic CAR-T cell therapy in the clinic, to Caribou's knowledge, with a PD-1 knockout, a genome-editing strategy designed to improve antitumor activity by limiting premature CAR-T cell exhaustion. CB-010 is also the first anti-CD19 allogeneic CAR-T cell therapy, to Caribou's knowledge, to be evaluated clinically in the second-line setting and 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 the second 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 technology. 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* 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 the third product candidate from Caribou's allogeneic CAR-T cell therapy platform and is being evaluated in investigational new drug (IND)-enabling studies. CB-012 is the first allogeneic CAR-T cell therapy, to Caribou's knowledge, 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. CB-012 is 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.

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 have exhibited editing at 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.

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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 expectations regarding 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 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)

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 290,990	$ 317,036
Total assets	347,462	373,765
Total liabilities	69,190	72,894
Total stockholders' equity	278,272	300,871
Total liabilities and stockholders' equity	$ 347,462	$ 373,765

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

	Three Months Ended, March 31,	
	2023	2022
Licensing and collaboration revenue	$ 3,502	$ 2,664
Operating expenses:		
Research and development	25,709	13,924
General and administrative	8,909	9,593
Total operating expenses	34,618	23,517
Loss from operations	(31,116)	(20,853)
Other income (expense):		
Change in fair value of equity securities	(15)	(88)
Change in fair value of the MSKCC success payments liability	255	1,596
Other income, net	2,832	257
Total other income	3,072	1,765
Net loss	$ (28,044)	$ (19,088)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on available-for-sale marketable securities, net of tax	788	(954)
Net comprehensive loss	$ (27,256)	$ (20,042)
Net loss per share, basic and diluted	$ (0.46)	$ (0.32)
Weighted-average common shares outstanding, basic and diluted	61,186,514	60,546,170

Caribou Biosciences, Inc. Contacts:
Investors:
Amy Figueroa, CFA
investor.relations@cariboubio.com

Media:
Peggy Vorwald, PhD
media@cariboubio.com