



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

August 8, 2023

-- CB-010 ANTLER trial dose expansion enrolling second-line LBCL patients; plan to share FDA feedback by YE 2023 and report initial dose expansion data in H1 2024 --

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

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

-- Received \$25.0 million equity investment from Pfizer --

-- Closed upsized public offering including full exercise of underwriters' option to purchase additional shares, delivering \$134.6 million in net proceeds

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-- More than \$400 million in cash, cash equivalents, and marketable securities following recent public offering; expected to fund the current operating plan into Q4 2025 --

BERKELEY, Calif., Aug. 08, 2023 (GLOBE NEWSWIRE) -- Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today reported financial results for the second quarter of 2023 and reviewed recent business updates.

"In 2023, we have advanced our programs to build value across the pipeline and position Caribou for continued momentum ahead," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "For our lead program, we are excited by the positive CB-010 dose escalation data demonstrating response rates that rival those from the approved autologous CAR-T cell therapies. As we develop CB-010 for the larger second-line LBCL patient population, we continue to enroll patients in dose expansion and anticipate reporting initial dose expansion data in the first half of 2024. We also look forward to meeting with the FDA later this year to discuss a potential pivotal clinical trial in second-line LBCL patients. Additionally, we continue to enroll patients in our CaMMouflage trial for CB-011 and plan for an IND submission for CB-012 in the second half of this year."

Accomplishments and highlights

Pipeline and technology

- **CB-010:** Caribou [reported](#) long-term follow-up data from all 16 patients treated in dose escalation of the ongoing ANTLER Phase 1 clinical trial of CB-010, an allogeneic anti-CD19 CAR-T cell therapy. In ANTLER dose escalation, three dose levels of CB-010 were evaluated (40x10⁶, 80x10⁶, and 120x10⁶ CAR-T cells) in patients with multiple subtypes of aggressive relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). As of the June 20, 2023 data cutoff date, results demonstrated:
 - CB-010 was generally well tolerated with adverse events consistent with autologous and allogeneic anti-CD19 CAR-T cell therapies.
 - 94% overall response rate (ORR; 15 of 16 patients) was observed following a single dose of CB-010.
 - 69% of patients (11 of 16) achieved a complete response (CR).
 - 44% of patients (7 of 16) had a CR at ≥6 months; 24 months is the longest CR maintained to date.
 - For the subset of patients with large B cell lymphoma (LBCL) (N=10):
 - A 90% ORR (9 of 10) was observed.
 - 70% (7 of 10) achieved a CR.
 - 50% (5 of 10) had a CR at ≥6 months; 18 months is the longest CR maintained to date.
 - Based on these positive data, Caribou is enrolling second-line patients with LBCL in the ongoing dose expansion portion of the ANTLER clinical trial. In expansion, the mid dose and the high dose from escalation (80x10⁶ and 120x10⁶ CAR-T cells) are being evaluated 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 ANTLER.
- **CB-011:** Caribou is enrolling patients at dose level 1 (50x10⁶ 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).
- **CB-012:** Caribou is advancing IND-enabling activities for CB-012, an allogeneic anti-CLL-1 CAR-T cell therapy, for relapsed or refractory acute myeloid leukemia (r/r AML).

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 YE 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 submit an IND application for r/r AML in H2 2023.

Corporate updates

- **\$25.0 million Pfizer investment:** On June 30, 2023, Pfizer [invested](#) \$25.0 million in Caribou common shares. In conjunction with the investment, Sriram Krishnaswami, PhD, joined [Caribou's scientific advisory board](#). 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.
- **Completed successful \$134.6 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 approximate net proceeds to Caribou were \$134.6 million.

Second quarter 2023 financial results

Cash, cash equivalents, and marketable securities: Caribou had \$292.5 million in cash, cash equivalents, and marketable securities as of June 30, 2023, which included the \$25.0 million proceeds from the Pfizer investment, compared to \$317.0 million as of December 31, 2022. This amount does not include the approximately \$134.6 million in net proceeds from the Company's underwritten public offering completed in the third quarter of 2023. Caribou expects its cash, cash equivalents, marketable securities, and net proceeds from the recent public offering 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 \$3.8 million for the three months ended June 30, 2023, compared to \$4.2 million for the same period in 2022. The decrease was primarily due to a reduction in revenue recognized under the AbbVie Collaboration and License Agreement, partially offset by a revenue increase related to a veterinary therapeutics licensing agreement.

R&D expenses: Research and development expenses were \$26.5 million for the three months ended June 30, 2023, compared to \$22.6 million for the same period in 2022. The increase was primarily due to personnel-related expenses, including stock-based compensation; costs to advance pipeline programs, including the ANTLER and CaMMouflage Phase 1 trials; and facilities and other allocated expenses.

G&A expenses: General and administrative expenses were \$10.1 million for the three months ended June 30, 2023, compared to \$10.0 million for the same period in 2022. The increase was primarily due to facilities and other allocated expenses; patent prosecution and maintenance costs; and personnel-related expenses, including stock-based compensation, due to headcount increases. The increase was partially offset by lower insurance and legal expenses.

Net loss: Caribou reported a net loss of \$29.5 million for the three months ended June 30, 2023, compared to \$26.7 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. 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 also 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 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. 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 the third product candidate from Caribou's allogeneic CAR-T cell therapy platform and is being evaluated in investigational new drug (IND)-enabling studies. 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. 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 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 (chRDNA; 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 chRNA 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, expectations about product developments in 2023, and expectations regarding the submission of an IND application 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)

	June 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	\$ 292,521	\$ 317,036
Total assets	<u>349,647</u>	<u>373,765</u>
Total liabilities	80,189	72,894
Total stockholders' equity	269,458	300,871
Total liabilities and stockholders' equity	<u>\$ 349,647</u>	<u>\$ 373,765</u>

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

	Three Months Ended, June 30,		Six Months Ended, June 30,	
	2023	2022	2023	2022
Licensing and collaboration revenue	\$ 3,755	\$ 4,192	\$ 7,257	\$ 6,856
Operating expenses:				
Research and development	26,503	22,579	52,212	36,503
General and administrative	10,120	10,044	19,029	19,637
Total operating expenses	<u>36,623</u>	<u>32,623</u>	<u>71,241</u>	<u>56,140</u>
Loss from operations	(32,868)	(28,431)	(63,984)	(49,284)
Other income (expense):				
Change in fair value of equity securities	22	(16)	7	(104)
Change in fair value of the MSKCC success payments liability	279	1,052	534	2,648
Other income, net	3,048	698	5,880	955
Total other income	<u>3,349</u>	<u>1,734</u>	<u>6,421</u>	<u>3,499</u>
Net loss	<u>\$ (29,519)</u>	<u>\$ (26,697)</u>	<u>\$ (57,563)</u>	<u>\$ (45,785)</u>
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale marketable securities, net of tax	(406)	(492)	382	(1,446)

Net comprehensive loss	<u>\$ (29,925)</u>	<u>\$ (27,189)</u>	<u>\$ (57,181)</u>	<u>\$ (47,231)</u>
Net loss per share, basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.44)</u>	<u>\$ (0.94)</u>	<u>\$ (0.75)</u>
Weighted-average common shares outstanding, basic and diluted	<u>61,417,934</u>	<u>60,757,689</u>	<u>61,302,863</u>	<u>60,652,532</u>

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