



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

November 7, 2023

-- 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, Calif., Nov. 07, 2023 (GLOBE NEWSWIRE) -- 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 (25×10^6 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](#) 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](#) 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](#) \$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 in 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, HGBL, 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 (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 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)

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

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

	<u>Three Months Ended, September 30,</u>		<u>Nine Months Ended, September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Licensing and collaboration revenue	\$ 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	<u>38,295</u>	<u>29,840</u>	<u>109,536</u>	<u>85,980</u>
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)	<u>4,631</u>	<u>(110)</u>	<u>11,052</u>	<u>3,389</u>
Net loss	<u>\$ (10,002)</u>	<u>\$ (26,647)</u>	<u>\$ (67,565)</u>	<u>\$ (72,432)</u>
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	<u>\$ (9,847)</u>	<u>\$ (27,101)</u>	<u>\$ (67,028)</u>	<u>\$ (74,332)</u>
Net loss per share, basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.44)</u>	<u>\$ (0.98)</u>	<u>\$ (1.19)</u>

Weighted-average common shares outstanding, basic and diluted

83,783,992	60,886,921	68,878,921	60,731,520
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