CARGO Therapeutics Reports Business Updates and Third Quarter 2023 Results

SAN MATEO, Calif., December 13, 2023 – CARGO Therapeutics, Inc. (Nasdaq: CRGX), a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients, today reported business updates and its financial results for the third quarter ended September 30, 2023.

“This year has been transformational for our company. We experienced growth across our business, including expanding our leadership team, commencing a Phase 2 clinical trial of CRG-022, and becoming a publicly traded company,” said Gina Chapman, President and Chief Executive Officer of CARGO. “While CAR T-cell therapies have changed the treatment landscape for patients with LBCL, patients whose disease relapses or is refractory to CD19 CAR T-cell therapy face a median survival of less than 6 months. We continue to believe that CRG-022 has the potential to alter the treatment paradigm for patients whose disease has relapsed or is refractory to CD19 CAR T. We are very pleased to have started our Phase 2 clinical trial which represents a key milestone as we work toward our goal of developing and delivering potentially curative therapies to more patients."

Third Quarter and Subsequent Highlights

Phase 2 Clinical Trial of CRG-022 CAR T-Cell Therapy in Patients with Relapsed or Refractory (R/R) Large B-cell Lymphoma (LBCL): CARGO announced that it has dosed the first seven patients in its potentially pivotal Phase 2 multicenter clinical trial (NCT05972720) after successfully manufacturing CRG-022, the Company’s autologous CD22 chimeric antigen receptor (CAR) T-cell product candidate. CD22 is a common B-cell antigen widely expressed in the vast majority of B-cell malignancies, including LBCL. The clinical trial is an open-label, multicenter Phase 2 clinical trial evaluating the efficacy and safety of CRG-022 in patients with R/R LBCL whose disease has progressed after CD19-directed CAR T-cell therapy, an area of high unmet need.

- The Phase 2 clinical trial is designed to treat up to 123 patients with a single infusion of CRG-022 across clinical sites in the United States. Clinical trial sites are opening rapidly, with 12 sites currently recruiting patients. The primary endpoint is overall response rate (ORR). Secondary endpoints include additional efficacy, safety, pharmacology, and manufacturing feasibility measures.
- Prior to starting the clinical trial, CARGO implemented process and method improvements to establish the intended commercial manufacturing process in order to minimize the need for changes post-pivotal trial.
- The Phase 2 clinical trial of CRG-022 is informed by positive initial results from a Phase 1 clinical trial being conducted by Stanford University (Stanford) evaluating CRG-022 in patients with LBCL that was R/R to CD19 CAR T-cell therapy.
- Interim results from CARGO’s Phase 2 trial are anticipated in 2025.

Phase 1 Clinical Trial Updates: During the American Society of Hematology (ASH) 2023 Annual Meeting in early December, Stanford shared updated data from its ongoing Phase 1 clinical trial in patients with LBCL that was R/R to CD19 CAR T-cell therapy (NCT04088890). The update reflects a recent data cut-off as of November 4, 2023. The previous data cut-off was May 3, 2023. The updated data that was shared included:

- For all patients treated (n=38), the ORR and CR rates were 68% and 53% respectively.
- The November 2023 data cut-off now provides a median follow-up of 27.3 months and includes the following new information from Stanford:
    - Since the May 2023 data cut-off, one additional patient relapsed after a remission duration of 21 months.
    - At Dose Level 1 (the dose CARGO is using for its Phase 2 clinical trial), 73% of patients who achieved a CR maintained the CR for at least 12 months (29 patients were treated at Dose Level 1; 15 achieved a CR, 11 of whom maintained a CR for ≥ 12 months).
    - At Dose Level 2, 9 patients were treated with 5 patients achieving a CR. Four of these 5 patients have maintained a CR for 12 months or longer.
    - With a median follow-up of 27.3 months, for Dose Level 1, the median OS has not been reached and for Dose Level 2, the median OS is 14.1 months.
    - Five patients who died of non-relapse causes were in CR at the time of death; 2 of 5 patients were in Dose Level 1 and 3 of 5 patients were in Dose Level 2.

Other Corporate Highlights

- Entered into a lease agreement for 99,557 square feet of lab and office space in San Carlos, California in December 2023. The lease is expected to commence in January 2024 with an initial term through March 31, 2031, and provides options to renew the lease for two additional three-year terms.
- Successfully completed an initial public offering (IPO) raising approximately $291 million in net proceeds.
- Strengthened the leadership team with the hiring of Ginna Laport, MD, as Chief Medical Officer who is responsible for providing leadership and direction to guide clinical development strategy, and Michael Ports, PhD, as Chief Scientific Officer who is responsible for advancing the Company's proprietary platform technologies and discovery-stage programs.
- Announced the formation of a Scientific Advisory Board comprised of experts in cancer research, immunology, and CAR T-cell therapy.

Third Quarter 2023 Financial Results

- As of September 30, 2023, CARGO had cash and cash equivalents of $60.3 million and approximately $438 million, as adjusted for the net proceeds from the third tranche of the Company’s Series A financing in October and its IPO in November which it expects will fund operations through 2025.
- Research and development (R&D) expenses were $22.2 million for the quarter ended September 30, 2023, compared to $8.5 million for the same period in 2022. The increase was primarily driven by an increase in contract manufacturing, preclinical, and clinical costs for the CRG-022 program and increased headcount in research and development teams to support development efforts.
- General and administrative (G&A) expenses were $6.5 million for the quarter ended September 30, 2023, compared to $1.6 million for the same period in 2022. The increase was primarily attributable to the expansion of administrative functions to support business operations and to prepare CARGO to operate as a public company.
- Net loss was $35.5 million, or $47.37 per basic and diluted share, for the quarter ended September 30, 2023. This compares with a net loss of $12.3 million, or $28.38 per basic and diluted share for the quarter ended September 30, 2022.

Upcoming Events

CARGO will participate in the 42nd Annual J.P. Morgan Healthcare Conference, taking place January 8-11, 2024, in San Francisco, California. Gina Chapman, President and Chief Executive Officer, is scheduled to present on Monday, January 8, at 9:45 AM PT.

About Large B-Cell Lymphoma (LBCL)

Lymphoma that affects B lymphocytes are called B-cell lymphomas. B-cells make antibodies to fight infections and are an important part of the human immune system. B-cell lymphomas account for approximately 85% of non-Hodgkin lymphomas (NHL) in the United States. LBCL is an aggressive (fast-growing) lymphoma that occurs most commonly in people over the age of 60, though it can occur in childhood.

About CRG-022

CRG-022 is CARGO's investigational cell therapy that is composed of autologous T-cells transduced with a lentiviral vector (m971-BBZ) expressing a CD22-targeting CAR. CD22 is a transmembrane protein expressed on normal B-cells and B-cell malignancies. Results of an ongoing Phase 1 clinical trial in adults demonstrate the safety and antitumor activity of CRG-022 in patients with LBCL whose disease is relapsed or refractory (R/R) to CD19 CAR T-cell therapy. Based on Phase 1 results, Stanford University was granted Breakthrough Therapy Designation from the FDA for the treatment of adult LBCL patients whose disease is R/R after CD19-directed CAR T-cell therapy. CRG-022 has a unique design which is associated with efficacy in the clinic that has not been seen with other CD22 CAR Ts. CARGO believes that CRG-022 has the potential to safely and effectively treat LBCL, including patients for whom prior CD19 CAR T-cell therapies have failed.

About CARGO Therapeutics

CARGO Therapeutics, Inc. is a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients. CARGO's programs, platform technologies, and manufacturing strategy are designed to directly address the limitations of approved cell therapies, including limited durability of effect, safety concerns and unreliable supply. CARGO is currently evaluating its lead program, CRG-022, an autologous CD22 chimeric antigen receptor (CAR) T-cell therapy candidate, in a potentially pivotal Phase 2 clinical trial in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy. CARGO also plans to evaluate CRG-022 in patients at earlier stages of disease, including LBCL and other hematologic malignancies. Beyond its lead program, CARGO is leveraging its proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic "cargo" designed to enhance CAR T-cell persistence and trafficking to tumor lesions, as well as to help safeguard against tumor resistance and T-cell exhaustion. CARGO's founders are pioneers and world-class experts in CAR T-cell therapy, and its team has significant experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products. For more information, please visit the CARGO Therapeutics website at https://cargo-tx.com/.

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Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements about: advancement of CARGO's clinical programs; the potential benefits from treatment with CD19 CAR T-cell therapies; timing of data reports including the release of interim data from the Company's ongoing Phase 2 clinical trial of CRG-022; and the implementation of CARGO's strategic plans for its business and product candidates, including additional indications which the company may pursue; and whether the Company's cash and cash equivalents will be able to fund operations through 2025. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the company's ability to obtain necessary capital to fund its clinical programs; the early stages of clinical development of the company's product candidates; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers, including CROs; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled Risk Factors" contained in the company's prospectus filed with the Securities and Exchange Commission (SEC) on November 13, 2023, pursuant to Rule 424(b) under the Securities Act and the company's other filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

CARGO THERAPEUTICS

CARGO Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(Unaudited)

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 22,233	$ 8,469	$ 48,724	$ 20,142
General and administrative	6,478	1,580	13,030	3,624
Total operating expenses	28,711	10,049	61,754	23,766
Loss from operations	(28,711)	(10,049)	(61,754)	(23,766)
Interest expense	—	(1,458)	(1,604)	(2,234)
Net change in fair value of redeemable convertible preferred stock tranche obligations	(7,651)	—	(8,343)	—
Change in fair value of derivative liabilities	—	(779)	6,453	(1,186)
Loss on extinguishment of convertible notes	—	—	(2,316)	—
Other income (expense), net	891	1	1,494	(16)
Net loss and comprehensive loss	$ (35,471)	$ (12,285)	$ (66,070)	$ (27,202)
Net loss per share attributable to common stockholders, basic and diluted	$ (47.37)	$ (28.38)	$ (98.15)	$ (79.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	748,862	432,835	673,175	343,635

CARGO Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	September 30,2023 (Unaudited)	December 31,2022
Assets		
Cash and cash equivalents	$ 60,344	$ 1,872
Prepaid expenses and other current assets	3,072	2,055
Operating lease right-of-use assets	2,825	2,165
Property and equipment, net	9,150	3,368
Other non-current assets	7,021	783
Total assets	$ 82,412	$ 10,243
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities	$ 41,134	$ 44,137
Long-term liabilities	525	1,342
Redeemable convertible preferred stock	150,088	—
Total stockholders' deficit	(109,335)	(35,236)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 82,412	$ 10,243

CARGO THERAPEUTICS

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