

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 21, 2024

CARGO Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41859
(Commission File Number)

84-4080422
(IRS Employer
Identification No.)

1900 Alameda De Las Pulgas
Suite 350

San Mateo, California
(Address of Principal Executive Offices)

94403
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 379-6143

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	CRGX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 21, 2024, CARGO Therapeutics, Inc. (the “Company”) announced its financial results for the year ended December 31, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to this Item 2.02 of this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.

99.1 [Press Release, dated March 21, 2024.](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARGO THERAPEUTICS, INC.

Date: March 21, 2024

By: /s/Gina Chapman

Gina Chapman
Chief Executive Officer



CARGO Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

– Potentially pivotal Phase 2 clinical study FIRCE-1 of firicabtagene autoleucl (CRG-022) is rapidly recruiting with 20 sites open to date; interim results expected 1H 2025 –

SAN MATEO, Calif., March 21, 2024 – CARGO Therapeutics, Inc. (Nasdaq: CRGX), a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients, today provided a business update and reported financial results for the quarter and year ending December 31, 2023.

To date, 20 sites have been initiated and are enrolling for the potentially pivotal Phase 2 clinical study, FIRCE-1. The Phase 2 trial (NCT05972720) is an open-label, multicenter Phase 2 clinical study evaluating the efficacy and safety of firicabtagene autoleucl (firi-cel) (CRG-022) in patients with relapse or refractory (R/R) large B-cell lymphoma (LBCL) whose disease has progressed after CD19-directed CAR T-cell therapy, an area of high unmet need. Interim results are anticipated in the first half of 2025.

“2023 was a transformative year for CARGO as we built our leadership team and attracted top talent, initiated FIRCE-1, a potentially pivotal Phase 2 clinical study of CRG-022, which we are now calling firi-cel, and executed a successful private financing and IPO, fortifying a strong financial position,” said Gina Chapman, President and Chief Executive Officer of CARGO. “Our team has the expertise and experience to engineer, develop and deliver a next generation of potentially curative therapies to patients with high unmet need in cancer with a commercial-ready manufacturing process.”

In December 2023, CARGO summarized results regarding an ongoing Phase 1 clinical study (being conducted by Stanford University (Stanford)) (NCT04088890) in patients with LBCL that were R/R to CD19 CAR T-cell therapy. At Dose Level 1 (n=29), the dose CARGO is using for its Phase 2 clinical trial, firi-cel (CRG-022) was well-tolerated and complete response (CR) rate was 52%, with 73% of patients who achieved a CR maintaining CR for at least 12 months, as of the November 4, 2023 cut-off date.

Other Corporate Highlights

- Completed an initial public offering (IPO) raising approximately \$291.0 million in net proceeds.
 - Added to the Russell 2000® Index on March 15, 2024.
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Fourth Quarter and Year-End Financial Results

- CARGO had \$405.7 million in cash and cash equivalents as of December 31, 2023, which it expects will fund operations through 2025.
- Research and development (R&D) expenses were \$27.1 million for the fourth quarter of 2023, which includes \$0.7 million of non-cash stock-based compensation expense. For 2023, R&D expenses were \$75.8 million, which includes \$1.3 million of non-cash stock-based compensation expense.
- General and administrative (G&A) expenses were \$7.9 million for the fourth quarter of 2023, which includes \$1.0 million of non-cash stock-based compensation expense. For 2023, G&A expenses were \$20.9 million, which includes \$2.0 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2023 was \$32.1 million, or \$1.49 per share, including non-cash stock-based compensation and depreciation expenses of \$1.7 million and \$0.5 million, respectively. For 2023, net loss was \$98.1 million, or \$16.53 per share, including non-cash stock-based compensation and depreciation expenses of \$3.3 million and \$1.5 million, respectively.

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, firicabtagene autoleucel (firi-cel) (CRG-022), an autologous CD22 chimeric antigen receptor (CAR) T-cell therapy candidate, in a potentially pivotal Phase 2 clinical study 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 firi-cel (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/>.

Follow us on LinkedIn: CARGO Therapeutics

Follow us on X (Twitter): @CARGOTx

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; the implementation of CARGO's strategic plans for its business and product candidates; 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, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 27,067	\$ 9,231	\$ 75,791	\$ 29,373
General and administrative	7,889	1,774	20,919	5,398
Total operating expenses	34,956	11,005	96,710	34,771
Loss from operations	(34,956)	(11,005)	(96,710)	(34,771)
Other income (expense), net	2,879	(2,744)	(1,437)	(6,180)
Net loss and comprehensive loss	\$ (32,077)	\$ (13,749)	\$ (98,147)	\$ (40,951)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.49)	\$ (25.62)	\$ (16.53)	\$ (104.40)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	21,563,893	536,579	5,938,782	392,268

CARGO Therapeutics, Inc.
Condensed Balance Sheet Data
(in thousands)

	December 31,	
	2023	2022
Assets		
Cash and cash equivalents	\$ 405,732	\$ 1,872
Other assets	47,304	8,371
Total assets	\$ 453,036	\$ 10,243
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Liabilities	\$ 47,650	\$ 45,479
Stockholders' equity (deficit)	405,386	(35,236)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 453,036	\$ 10,243

Find more information at cargo-tx.com
Follow us on LinkedIn: CARGO Therapeutics
Follow us on X (Twitter): @CARGOTx

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