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): January 10, 2025

CARGO Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41859**	**84-4080422**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

835 Industrial Road **Suite 400** **San Carlos, California**	**94070**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 499-8950

(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.

In connection with its participation in the 43rd Annual J.P. Morgan Healthcare Conference, on January 10, 2025, CARGO Therapeutics, Inc. (the "Company") issued a press release announcing certain corporate updates, anticipated milestones for 2025, and estimated cash, cash equivalents and marketable securities of approximately $368.1 million as of December 31, 2024. The Company's actual cash, cash equivalents, marketable securities as of December 31, 2024 may differ from this estimate due to the completion of the Company's year-end closing and auditing procedures.

Spokespersons of the Company will be presenting the information provided in this item 2.02 of this Form 8-K at various upcoming meetings beginning January 13, 2025.

The information provided in 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.	Description
99.1	Press Release, dated January 10, 2025.
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: January 10, 2025

By: /s/ Gina Chapman
Gina Chapman
Chief Executive Officer

Exhibit 99.1

CARGO Therapeutics Provides Corporate Update and Anticipated Milestones for 2025

- 71 patients dosed in the potentially pivotal Phase 2 clinical study of firicabtagene autoleucel (firi-cel); Interim analysis results expected to be reported in 1H'25 -

- IND application for CRG-023, CARGO's tri-specific CAR T, cleared by the FDA; Phase 1 study enrollment expected to initiate mid-year 2025 -

- CARGO announces novel allogeneic platform based on a universal allogeneic-enabling vector intended to be paired with any new or existing CAR vector to create an allogeneic CAR T-cell therapy while leveraging existing autologous drug product processes -

SAN CARLOS, Calif., January 10, 2025 – **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 corporate update and anticipated milestones for 2025.

"2024 highlighted our excellence in execution and innovation. We now have three programs – two clinical-stage with another advancing quickly – all driven by our strong capabilities designing, developing, and delivering next-generation, and potentially curative cell therapies," said Gina Chapman, President and Chief Executive Officer of CARGO. "We are on track to report our interim analysis results for FIRCE-1 in first half 2025. I am also delighted to announce the clearance of our IND for CRG-023, a potentially best-in-class CAR T-cell therapy with Phase 1 enrollment to initiate mid-year. Rapid progression of CRG-023 from lead construct to IND submission in less than 12 months was enabled by our robust CMC and pre-clinical development capabilities. Finally, I'm very excited to announce our novel allogeneic platform, which I believe can meaningfully improve the availability of potentially curative cell therapies for patients by realizing the promise of an allogeneic solution in a universally applicable way. I'd like to thank the entire CARGO organization for their tenacity and innovative spirit, positioning us for our important milestones this year."

“The challenges that limit a broader impact for autologous cell therapy include the quality of T cells derived from sick patients and availability of product. For allogeneic cell therapy, durable efficacy has been difficult to achieve,” said Michael Ports, Chief Scientific Officer of CARGO. “Over the past three years, we set out to solve these limitations through sophisticated cell therapy design and engineering, starting with CRG-023 and now with our novel allogenic platform that is intended to address immune-based rejection of allogeneic CAR T. The allogeneic CAR T platform is comprised of a universal vector with multiple transgene “cargo” to limit T and NK rejection and downregulate TCR. Importantly, the vector can be paired with pre-existing CAR vectors across targets and indications and can leverage existing autologous drug product processes. We are encouraged by our preclinical results which suggest the potential of a universal approach to creating off-the-shelf allogeneic CAR T products to provide more life-saving therapies for patients.”

Corporate Update and Anticipated Milestones for 2025:

Firi-cel:

- As of December 31, 2024, 71 patients have been dosed in the potentially pivotal Phase 2 study of firi-cel, FIRCE-1.
- CARGO continues to achieve strong manufacturing success of firi-cel. The Company is partnering with National Resilience, Inc. and ElevateBio to manufacture drug product for the FIRCE-1 study.
- CARGO expects to share topline data from an interim analysis for a meaningful patient sample size with at least 3 months of follow-up in 1H’25.

CRG-023:

- In January, the FDA cleared the Investigational New Drug (IND) application for CRG-023, CARGO’s novel tri-specific CAR T that is designed to address several known causes of relapse, resulting in a potential best-in-class CAR T-cell therapy across a broad range of B-cell malignancies with the goal of providing more patients with a durable complete response. CRG-023 is a first-of-its-kind CAR T to express three independent CARs (CD19, CD20, CD22) from a single vector, with each CAR having a distinct co-stimulatory domain. CRG-023 lentiviral vector is produced using suspension culture process which provides a line of sight to commercially suitable expression level. CRG-023 drug product is produced leveraging CARGO’s internally developed process and analytical methods.
- Given the encouraging pre-clinical data of CRG-023, CARGO intends to demonstrate the product candidate’s best-in-class potential through a Phase 1 dose escalation study in 3L+ LBCL including CAR T-naïve patients. The Company plans to leverage proof-of-concept data to support moving quickly into earlier lines of therapy and additional indications in B-cell malignancies for CRG-023.

- The Phase 1, open-label, multi-center, dose escalation and dose expansion study is expected to evaluate the safety, tolerability, pharmacokinetics, and efficacy of CRG-023 and to establish the recommended Phase 2 dose of CRG-023. Dose escalation will begin at a dose level of 25 million cells, which was informed by preclinical data that demonstrated in vivo tumor clearance at low dose levels. Enrollment for the Phase 1 study, including CAR T-naïve patients, is expected to initiate mid-year 2025. CARGO plans to leverage its established manufacturing and supply chain infrastructure to accelerate readiness for its Phase 1 study.

Novel Allogeneic Platform:

- CARGO's novel allogeneic platform is a universal vector solution designed to limit immune-based rejection and enable durable response of CAR T-cell therapy. Through sophisticated engineering, the differentiated platform aims to transform potentially curative autologous CAR T-cell therapies into allogeneic products for broader patient benefit. The universal, allogeneic-enabling vector is intended to pair with new or clinically established CAR vectors, which can be accomplished while leveraging existing autologous drug product processes. The result is intended to be an off-the-shelf allogeneic CAR T product designed to limit rejection, promote safety, improve the starting quality of T cells, and maintain comparable CAR-mediated activity.
- To date, CARGO has advanced several lead allogeneic constructs and demonstrated proof of concept in limiting immune rejection, preventing graft vs. host disease (GvHD), and preserving comparable CAR activity when co-transduced with CAR vector utilized for autologous CAR T-cell therapy.
- CARGO expects to select the lead vector candidate in 1H'25.

Financial Outlook:

- As of December 31, 2024, the Company's preliminary cash, cash equivalents and marketable securities were $368.1 million[(1)], which we believe will be sufficient to fund our expected operations through 2026.

Gina Chapman, President and Chief Executive Officer, is scheduled to present at the 43rd Annual J.P. Morgan Healthcare Conference on Monday, January 13, at 10:30 a.m. PT. Interested parties can access the live webcast for the presentation in the Investors section of CARGO's website under News & Events. A replay of the webcast will be available after the conclusion of the live presentation for approximately 30 days.

About CARGO Therapeutics

CARGO Therapeutics, Inc. is a clinical-stage biotechnology company positioned to advance next-generation, best-in-class, and 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 availability. CARGO has a growing and focused pipeline that includes firicabtagene autoleucel (firi-cel), an autologous CD22 chimeric antigen receptor (CAR) T-cell therapy candidate currently 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 is also preparing to initiate a Phase 1 study for its CRG-023 product candidate, a CD19/CD20/CD22 tri-specific CAR T developed using a tri-cistronic construct and designed to address several known causes of relapse, resulting in a potential best-in-class CAR T-cell therapy across a broad range of B-cell malignancies with the goal of providing more patients with a durable complete response. CARGO's latest program advancement, a novel allogeneic platform, is a universal vector solution designed to limit immune-based rejection and enable durable response of CAR T-cell therapy. The universal allogeneic-enabling vector is intended to be paired with any CAR vector to create an allogeneic CAR T-cell therapy, with the potential to maintain the efficacy, durability, and safety of autologous cell therapy while broadening availability to more people with cancer. CARGO's leadership and team have significant experience in designing, developing and delivering 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

(1) The Company's actual consolidated cash, cash equivalents, marketable securities as of December 31, 2024 may differ from this preliminary estimate due to the completion of the Company's year-end closing and auditing procedures.

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: the initiation, timing, progress, advancement, and results of CARGO's clinical and preclinical programs; the potential benefits of CARGO's product candidates; the timing of data reports, including the release of interim data from CARGO's ongoing Phase 2 clinical trial of firi-cel; CARGO's strategic plans for its business and product candidates; CARGO's estimated cash, cash equivalents and marketable securities as of December 31, 2024 and CARGO's expectations that its current cash, cash equivalents and marketable securities will be sufficient to fund its expected operations through 2026. 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 and the product candidates involving novel technologies; clinical and preclinical development being a lengthy and expensive process with uncertain outcomes; data from the company's clinical trials and preclinical studies, including the performance and characteristics of the company's product candidates, including any undesirable side effects or other properties discovered or detected in the company's clinical trials and preclinical studies; any favorable data from trials conducted by third-parties, including Stanford University or the NCI, may not be replicated in the company's clinical trials or predictive of future results; the company's ability to obtain regulatory approval of and successfully commercialize its 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. For a detailed discussion of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to CARGO's business in general, please refer to the risk factors identified in the Company's filings with the Securities and Exchange Commission (SEC), including but not limited to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 filed on November 12, 2024. 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.

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