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 8, 2024

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 Number)

1900 Alameda De Las Pulgas, Suite 350
San Mateo, California 94403
(Address of principal executive offices) (Zip Code)

(650) 379-6143
(Registrant's telephone number, including area code)

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, $0.001 par value 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 7.01 Regulation FD Disclosure.

On January 8, 2024, CARGO Therapeutics, Inc. (the "Company") made available a corporate presentation, which it plans to use for meetings with investors and analysts at the 42nd Annual J.P. Morgan Healthcare Conference. A copy of the presentation is being furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	CARGO Therapeutics Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

CARGO THERAPEUTICS, INC.

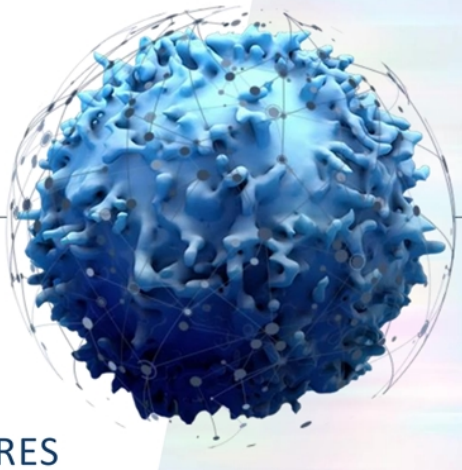
Date: January 8, 2024

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

Exhibit 99.1

NASDAQ: CRGX

CARGO THERAPEUTICS



ENGINEERING NEXT GENERATION CAR T-CELL THERAPIES TO DELIVER MORE CURES

J.P. MORGAN HEALTHCARE CONFERENCE 2024

FORWARD-LOOKING STATEMENTS/Disclaimers

- This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may include the words "believe", "expect", "anticipate", "intend", "plan", "estimate", "project", "will", "may", "targeting" and similar expressions as well as statements other than statements of historical facts including, without limitation, those regarding business strategy, plans, estimated milestones and objectives of the management of the Company. Such forward-looking statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks, including business, regulatory, econo and competitive risks, uncertainties, contingencies and assumptions about the Company, including, without limitation, risks inherent in developing CRG-022 or CRG-023, future results from the Company's ongoing and planned clinical trials, the Company's ability to obtain adequate financing to fund its planned clinical trials and other expenses, trends in the industry, the legal and regulatory framework for the industry and future expenditures. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The actual results may vary from the anticipated results and the variations may be material. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of the assumptions, fully stated in the presentation. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this presentation is given. These and other risks are described more fully in CARGO's filings with the Securities and Exchange Commission (SEC) including its Registration Statement on Form S-1 filed with the SEC on October 10, 2023 (and as subsequently amended) or in other documents CARGO subsequently files with or furnishes to the SEC. CARGO undertakes no duty or obligation to update any forward-looking statements as a result of new information, future events or changes in its expectations.
- Information in this presentation (including market data and statistical information) has been obtained from various sources (including third-party sources) and the Company does not guarantee the accuracy or completeness of such information. All projections, valuations and statistical analyses are provided for information purposes only. They may be based on subjective assessments and assumptions and may use one among many alternative methodologies that produce different results and to the extent they are based on historical information, they should not be relied upon as an accurate prediction of future performance, and you are cautioned not to give undue weight to them.
- This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the therapeutic use for which such product candidates are being studied.
- The Phase 1 clinical trial for CRG-022 referenced herein was conducted by Stanford using their formulation of CRG-022. The Company has made additional process and analytical improvements to the Stanford process to create the intended commercial manufacturing process for CRG-022 in an effort to improve manufacturing yields and efficiency.

CARGO – developing potentially curative cell therapies

Transformative and growing CAR T market

- Autologous CAR T revenue in DLBCL is **estimated to reach $3.3B by 2030**
- **Patient access is broadening** as more treatment centers offer CAR T

Significant unmet need post CD19 CAR T

- **CRG-022 may address the ~60% of LBCL patients who do not achieve a durable response** with CD19 CAR T-cell therapy[1]
- **By 2030, ~7,600 patients expected to need treatment** post CD19 CAR T-cell therapy in US/EU4/UK alone[2]

CRG-022: targeting CD22, potentially pivotal stage

- Positive Phase 1 results in CD19 CAR T R/R LBCL – **53% CR rate with impressive durability and safety**
- **120+ patients dosed** across multiple clinical trials and CRG-022 was **generally well-tolerated**
- **Initiated potentially pivotal Phase 2 clinical trial; multiple patients dosed with successful manufacturing to date,** leveraging our intended commercial and readily transferable manufacturing process
- Stanford was granted **Breakthrough Therapy Designation** by FDA

Platform technologies and tri-specific program

- Leveraging proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic "cargo" designed to address mechanisms of resistance
- CRG-023, an IND-enabling stage tri-specific targeting CD19, CD20 and CD22, incorporates first platform, which integrates a novel CD2 costimulatory domain to counter downregulation of CD58

World class team and well capitalized

- Co-founded in 2021 by **globally recognized pioneers and leaders in oncology and cell therapy**
- **Seasoned, strong leadership team** with deep cell therapy and oncology experience
- November 2023 IPO **raised approximately $320M gross proceeds**, NASDAQ ticker: CRGX

Source: Yi-Jiun Su, et al. ASH 2023, Nov'2023 data cutoff
Source: Five-year follow-up of ZUMA-1 trial; [1] N Engl J. Med 2017;377:2531-44 DOI: 10.1056/NEJMoa1707447; [2] Clarivate Disease and Landscape Forecasting (NHL, CLL) 2023; US/EU4/UK and CARGO company analysis

Pipeline of transformative CAR T-cell therapies to deliver cures - addressing mechanisms of resistance

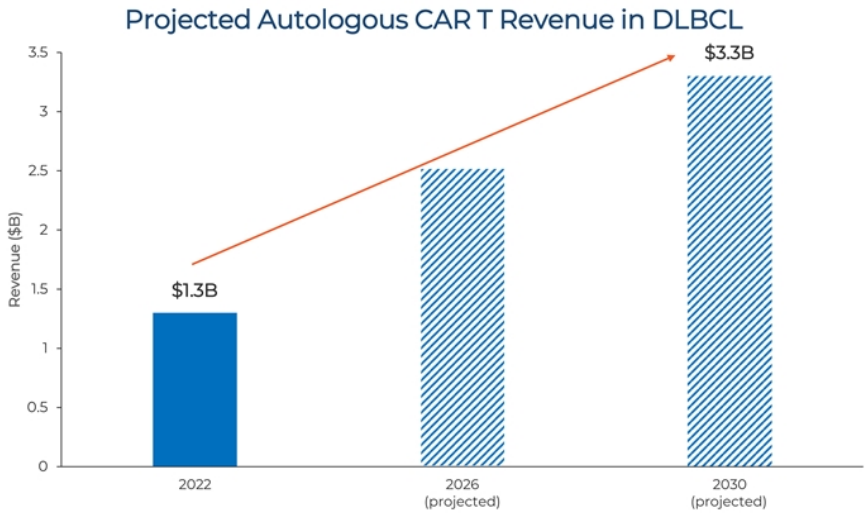
Resistance mechanism	Solutions
Antigen escape (e.g., CD19)	Target Alt Antigen or Multi-specific CAR designs
Loss of costimulation (e.g., CD58)	CAR-Engineered, CD2 technology
Immune rejection of product	Human binders
Tumor burden, loss of functional persistence	Design, lead selection and MFG

Potentially pivotal Phase 2 topline data for lead product candidate CRG-022 expected in 2025

			Stage of Development					
Program	Target(s)	Indication(s)	Discovery	IND-enabling	Phase 1	Phase 2	Phase 3	Commercial rights
CRG-022 *(CAR T)*	CD22	R/R LBCL - post CD19 CAR T						CARGO THERAPEUTICS
		LBCL - CAR T naïve[1]						
		Pediatric B-ALL						
CRG-023 *(tri-specific CAR T with CD2 co-stimulation)*	CD19 CD20 CD22	B-cell malignancies						CARGO THERAPEUTICS

[1] Based on data from the Phase 1 clinical trial conducted by Stanford and our ongoing Phase 2 clinical trial in R/R LBCL - post CD19 CAR T, we intend to discuss with the FDA initiation of a Phase 2 program in LBCL - CAR T naive without completing earlier clinical trials in LBCL - CAR T naive patients

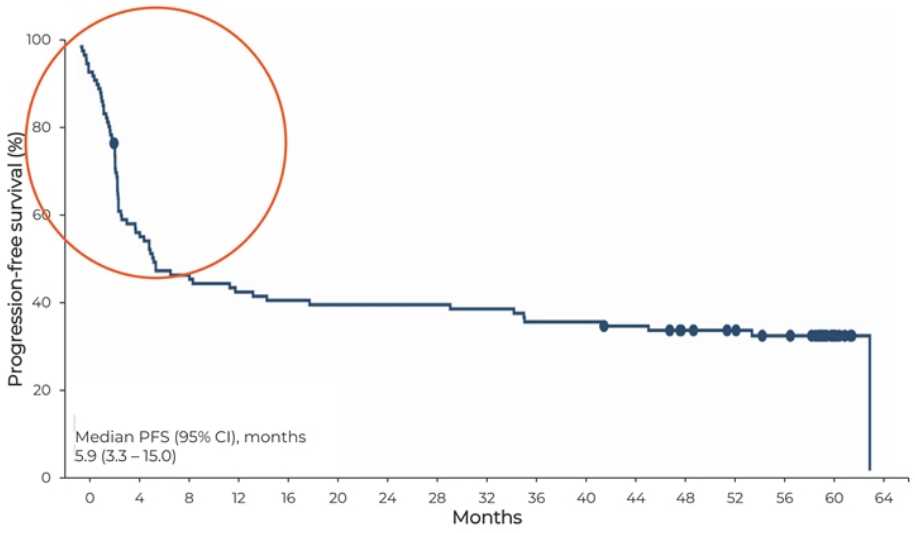
CD19 CAR T-cell therapy: transformative and growing



- Autologous CD19 CAR T-cell therapies to potentially become Standard of Care for relapsed / refractory Large B-Cell Lymphoma (R/R LBCL)
- Recent approvals in earlier lines of therapy and additional geographies anticipated to continue to fuel growth
- Patient access broadening as more treatment centers offer CAR T and manufacturing challenges are addressed

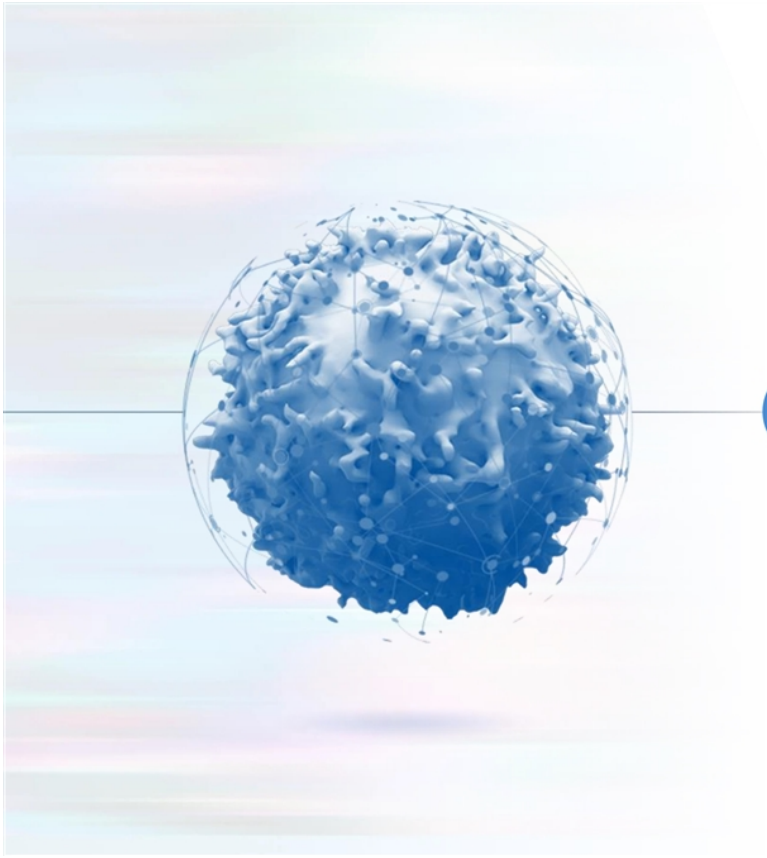
Source: Clarivate Disease and Landscape Forecasting (NHL, CLL) 2022; US/EU4/UK

CRG-022 could address a significant and growing unmet need for patients whose disease is R/R to CD19 CAR T-cell therapy



- ~60% of LBCL patients were observed to not achieve a durable response with CD19 CAR T-cell therapy[1]
- High unmet need with no standard of care for post CD19 CAR T patients and poor survival outcomes
- By 2030, approximately 7,600 patients expected to need treatment post CD19 CAR T-cell therapy in US/EU4/UK alone[2]

Source: Five-year follow-up of ZUMA-1 trial; [1] N Engl J. Med 2017;377:2531-44 DOI: 10.1056/NEJMoa1707447; [2] Clarivate Disease and Landscape Forecasting (NHL, CLL) 2023; US/EU4/UK and CARGO company analysis



CRG-022

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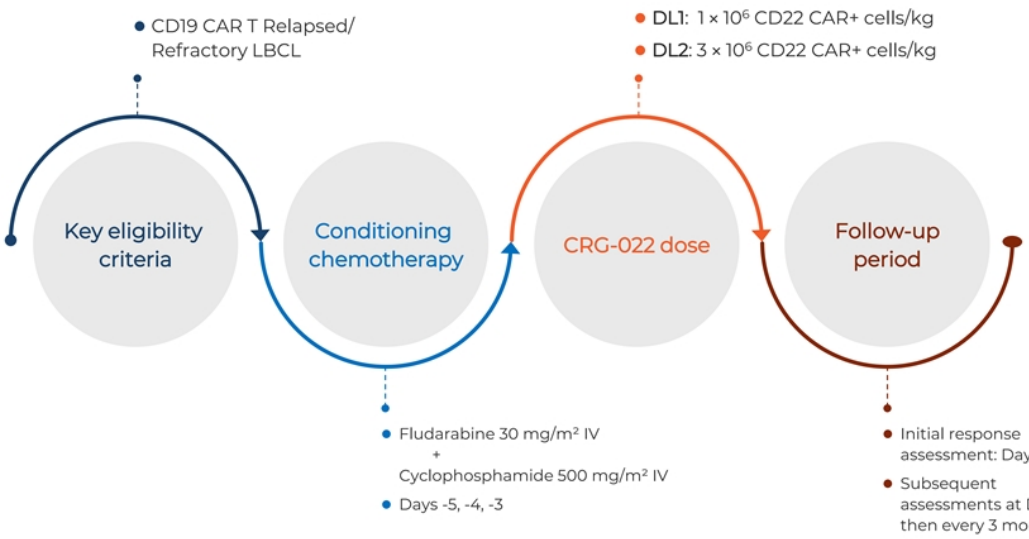
Phase 1 design: Stanford study of CRG-022 CAR T in R/R LBCL



Abbreviations: **CAR19** = anti-CD19 CAR T-cell therapy; **R/R** = relapsed or refractory; **CRG-022** = anti-CD22 CAR T-cell therapy; **DL** = dose level; **RP2D** = recommended phase 2 dose; **TEAE** = treatment-emergent adverse events; **ORR** = overall response rate; **DOR** = duration of response; **PFS** = progression free survival; **OS** = overall survival; **ULN** = upper limit of normal;
Note: Response was classified according to Lugano criteria for LBCL
Source: Cheson BD, et al. J Clin Oncol. 2014; 32(27):3059-67; Lee DW, et al. Biol Blood Marrow Transplant. 2019; 25(4):625-38; Frank MJ et al. EHA 2023

Baseline Characteristics of Treated Patients (N=38)

- 97% progressed after prior CD19 CAR T
- Median age 65 years old
- Median 4 prior lines of therapy
- 76% had DLBCL; 16% double-hit status
- 84% had elevated lactate dehydrogenase (high tumor burden)

Primary Endpoints

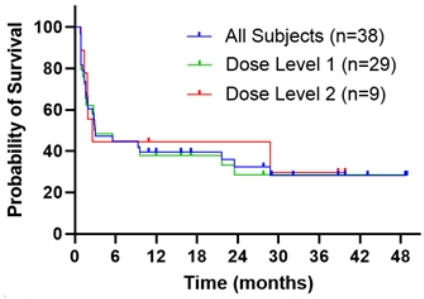
- Safety and toxicity (TEAEs)
- Recommended Phase 2 dose
- Manufacturing feasibility

Key Secondary Endpoints

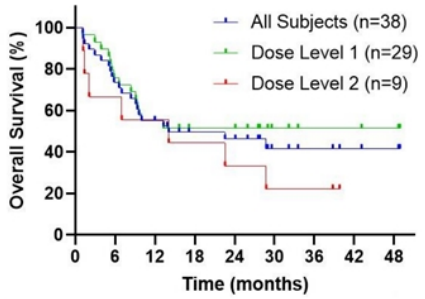
- ORR* (investigator-assessed)
- DOR/PFS/OS
- Pharmacokinetics

Phase 1 results: CRG-022 demonstrated potential to be an effective therapy for LBCL patients whose disease is R/R to CD19 CAR T-cell therapy

Progression free survival (PFS)



Overall survival (OS)



LBCL	DL1 (n=29)	DL2 (n=9)	Total (n=38)
Median follow up, months [range]	27.3 [12.0 – 48.9]	39.8 [35.1 – 43.9]	28.9 [12.0 – 48.9]
Overall Response Rate (ORR)*, n (%)	19 (66%)	7 (78%)	26 (68%)
CR rate	15 (52%)	5 (56%)	20 (53%)
12-mon duration of CR[1]	11/15 (73%)	4/5 (80%)	15/20 (75%)
Median OS, months [95% CI]	NR (8.4 – NR)	14.1 (1.2 – NR)	14.1 (8.4 – NR)

Source: Stanford Phase 1 data presentation at ASH Investigator meeting; Yi-Jiun Su, et al. ASH 2023; Nov'2023 data cutoff
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.
1) 2 patients relapsed. 3 patients died (1 related, 2 unrelated); NR: Not reached

Key Takeaways

- CR rate: **53%**
- ORR rate: **68%**
- CRs typically durable with only 4 of 20 pts who achieved a CR have relapsed

- Manufacturing success rate: **95%**
- Dose Level 1
  - 1 million CAR+ cells/kg
- Dose Level 2
  - 3 million CAR+ cells/kg

Phase 1 results: CRG-022 was generally well-tolerated

Parameter	DLBCL DL1 (n=29)	DLBCL DL2 (n=9)	Total n=38
Cytokine Release Syndrome, n (%)			
None	2 (7%)	0 (0%)	2 (5%)
Grade 1	13 (45%)	1 (11%)	14 (37%)
Grade 2	14 (48%)	7 (78%)	21 (55%)
Grade ≥3	**0 (0%)**	**1 (11%)**	**1 (3%)**
Neurologic Events / ICANS, n (%)			
None	26 (90%)	7 (78%)	33 (87%)
Grade 1	2 (7%)	1 (11%)	3 (8%)
Grade 2	1 (3%)	1 (11%)	2 (5%)
Grade ≥3	**0 (0%)**	**0 (0%)**	**0 (0%)**

Grade 3+ rates		
Approved CD19 CAR T-cell therapies[3]		
ZUMA-1 (axi-cel)	JULIET (tisagen)	TRANSCEND (liso-cel)
13%	22%	2%
28%	12%	10%

IEC-HS incidence
- DL1: 7%
- DL2: 33%
- Total: 18%

Managed with anakinra and steroids

Real world incidence of carHLH with CD19 CARs:
- Peds B-ALL: 14.8%
- DLBCL: 6%

Abbreviations: **IEC-HS** = Immune effector cell HLH-like syndrome; **carHLH** = Chimeric Antigen Receptor T-Cell-Associated Hemophagocytic Lymphohistiocytosis
Source: [1] Hines et al. 2021; [2] Ahmed et al. 2020; [3] Data reported from clinical studies for each approved therapy and not from head-to-head studies with CRG-022.
Source: Stanford Phase 1 data analysis shared at ASH 2023 Investigator meeting

Potentially pivotal Phase 2 clinical trial of CRG-022 in R/R LBCL

Currently enrolling

Key eligibility criteria

- R/R LBCL
- CD22 expression at any level

Cohort 1

- Prior CD19 CAR T-cell therapy (n=81)

Cohort 2

- Nonconforming product or dose

Cohort 3

- Prior Bispecific Abs (n=20) (including prior CD19 CAR T)

Conditioning chemotherapy

- Fludarabine + Cyclophosphamide
- Target CRG-022 cell dose: 1×10^6 CAR+ cells/kg

Endpoint

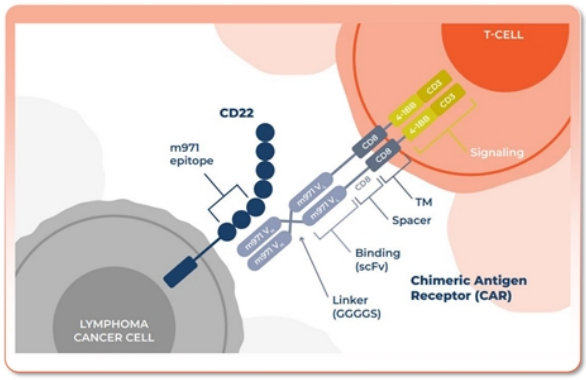
Primary endpoint

- ORR per PET/CT

Abbreviations: **LBCL** = large B-cell lymphoma; **R/R** = relapsed or refractory; **PET/CT** = positron emission tomography / computed tomography; **ORR** = overall response rate;

CRG-022: Differentiated CAR-mediated activity and commercially suitable manufacturing process

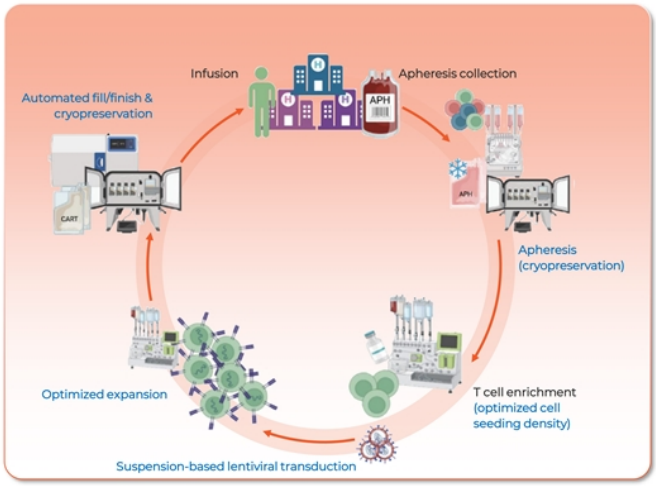
Design: Chimeric antigen receptor (CAR) has differentiated functional potential



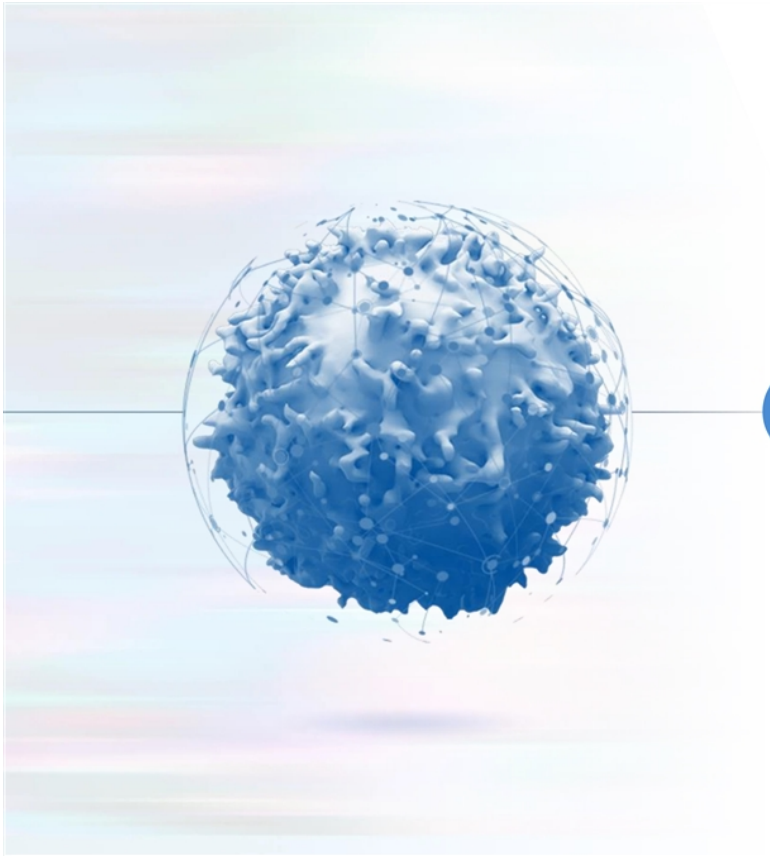
CD22
Unique Target to address CD19 antigen loss

Binder and costim domain
Beneficial antigen-independent signaling & enhanced persistence

Manufacturing: Address Commercial Suitability While Maintaining Product Comparability



*Source: Ereno-Orbea J, et al (2021) J Biol Chem 297(2): 100966; Singh N, et al (2021) Nat Med 27(5):842
BioRender



Pipeline & platform overview

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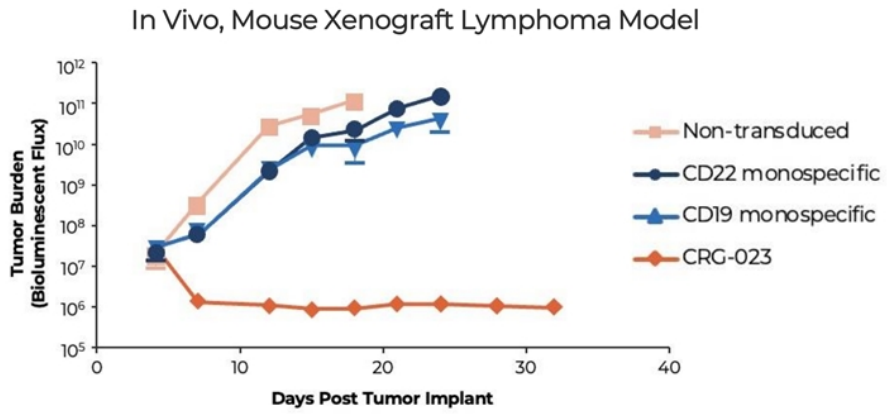
CARGO's pipeline: CRG-023, Tri-Specific CAR T targeting CD19, CD20, CD22



- 3 distinct CARs. Each with unique co-stimulatory domains, including 1 CAR with novel CD2 co-stim
- Expressed from 1 vector
- New Hu scFv binders for CD19, 20.
- 1000s of constructs screened

Model: **1:1:1 Raji CD19KO:CD20KO:CD22KO**

Seasoned leadership team with significant oncology and cell therapy experience

Gina Chapman
President & Chief Executive Officer
Genentech · Gilead

Anup Radhakrishnan
Chief Financial Officer & Chief Business Officer
dascena · Genentech · Elan

Ginna Laport, MD
Chief Medical Officer
Genentech · Tempest Therapeutics · Corvus Pharmaceuticals

Shishir Gadam, PhD
Chief Technical Officer
Genentech · Bristol Myers Squibb · Merck

Michael Ports, PhD
Chief Scientific Officer
Janssen · Juno · Celgene

Kari Leetch
Chief People Officer
ChemoCentryx · RMS · ThermoFisher Scientific

Halley Gilbert, JD
Chief Legal Officer
Cubist · Ironwood · Invivyd

Bethany Rogers
SVP, Product Strategy & Commercialization
Atara Bio · AbbVie · Pharmacyclics

CARGO – focused on developing and delivering potentially curative cell therapies

Key takeaways

- **Impressive Phase 1 results of CRG-022** in CD19 CAR T R/R LBCL
- **Currently enrolling potentially pivotal Phase 2 clinical trial,** with **topline data expected in 2025**
- Developed strong **commercial and readily transferable manufacturing process** for all clinical trials
- Leveraging **proprietary cell engineering platform technologies** to develop a **pipeline of programs**
- **Seasoned, strong leadership team**
- **Total cash at hand** (as of 31 Dec 2023): **$406M**

Strong financial position and significant value inflection points

● Raised **$320M in gross proceeds** following IPO	November 2023	✓
● Initiation of Phase 2 for CRG-022 in LBCL R/R CD19	August 2023	✓
● Interim Phase 2 results for CRG-022 in LBCL R/R CD19	2025 (expected)	

*Includes Series A Tranche 3
Note: As of May 3, 2023 data cutoff date

Thank you