United States securities and exchange commission logo

September 28, 2023

Halley Gilbert
Chief Legal Officer
CARGO Therapeutics, Inc.
1900 Alameda De Las Pulgas, Suite 350
San Mateo, CA 94403

Re: CARGO Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted September 1, 2023
CIK No. 0001966494

Dear Halley Gilbert:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary
Overview, page 1

1. Please disclose whether Stanford s Phase 1 clinical trial was powered for statistical significance, and whether any SAEs were observed. Please also disclose whether Stanford is a licensor, or otherwise advise.
2. We note your disclosure on page 2 that Stanford received Breakthrough Therapy Designation from the FDA. Please balance this disclosure with the statement on page 45 that a Breakthrough Therapy Designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that a product

candidate will receive FDA approval. Please also clarify whether your product candidate, CRG-022, has been designated by the FDA as a breakthrough therapy for the purposes of your IND application.
3. With regard to your disclosure that CRG-022 is being studied by Stanford in a Phase 1 clinical trial, please clarify, if known, whether Stanford plans to

pursue additional clinical
trials beyond its current Phase 1 clinical trial with a goal of
receiving regulatory approval
and how your and their trials will work in tandem, if at all.
4. We note your references to "breakthrough" and "encouraging" results
here, and
elsewhere. Please refrain from describing preliminary data from
clinical trials as
"breakthrough" or "encouraging" as this may create an inference that a
product candidate
is more likely to be found to be safe and effective and limit the
discussion to the objective
clinical data, such as the endpoints and whether they were met.
5. We note your disclosure on page 3 regarding demonstrating
comparability of the final
drug product to that produced by the process used in the Stanford
Phase 1 clinical trial.
Please balance this disclosure with the statements on page 45 and
elsewhere that you
cannot assure that the FDA will agree with your claim of comparability
and the
sufficiency of the data to support it, or agree with your ability to
reference the preclinical,
manufacturing or clinical data generated by the Stanford clinical
trial even if you obtain a
right of reference from Stanford.
6. Please revise your prospectus summary to explain briefly at first use
each of the scientific
or technical terms. By way of example only, we note the following
terms:

- Autologous
- Chimeric antigen receptor
- High Complete Response
- Cognate ligands
- Immune escape
- Payload capacity
- Lentiviral vector

Our solution: next generation of CAR T-cell therapies, page 3

7. We note your disclosure on page 4 that your team will implement
manufacturing
processes that are highly reliable and readily transferrable to expand
capacity, reduce
turnaround time and minimize costs of goods. Please balance this
disclosure with the
statements on page 25 that you may experience delays in developing a
sustainable,
reproducible and scalable manufacturing and page 55 that you do not
own or operate your
own manufacturing facilities, and rely on third-parties, which can
result in increased costs
that could delay, prevent, or impair development or commercialization
efforts.
Our history, team and investors, page 6

8. We note your disclosure that your team has progressed products from
research to clinical

trials, and ultimately to regulatory approval and commercialization.
Please balance this
disclosure with the statement on page 25 that novel products, such as
yours, can be more
complex and consequently more expensive and take longer than for
other, better known or
extensively studied pharmaceutical or other product candidates.
9. Please limit the disclosure of specific investors to those identified
in the beneficial
ownership table on page 194. Additionally, indicate that prospective
investors should not
rely on the named investors investment decisions, that these
investors may have different
risk tolerances and that the shares purchased in the referenced
financings may have been

conducted at a significant discount to the IPO price, if true.
Risk Factors Summary, page 7

10. We note your disclosure that you have experienced rapid growth since your inception, and that you expect to continue to grow in the future. Please specify the type of growth you are referencing in this disclosure. In this regard, we note your disclosure on page 22 appears to reference employee and operational growth.
Summary financial data, page 12

11. You disclose on page F-23 that the preferred stock will automatically be converted into common stock upon the IPO provided that the offering price per share is not less than $5.00 (as adjusted for stock dividend, stock split, combination or other similar recapitalization) and the aggregate gross proceeds to the Company are not less than $75.0 million, or at the date and time, or occurrence, of an event specified in a vote or written consent of the holders of the majority of the outstanding shares of convertible preferred stock. Tell us why it is appropriate to include the conversion in the pro forma column on page 14. If you believe the preferred stock will convert upon the IPO, please revise the disclosure to clarify the conditions in which the conversion will occur and tell us why you believe the conditions will be met.
Critical Accounting Policies and Significant Judgments and Estimates
Common Stock Valuations, page 120

12. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the awards underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock-based compensation. Please discuss with the staff how to submit your response.
Business
Our lead program, CRG-022, page 125

13. Please revise to clearly disclose the primary and secondary endpoints, if any, of the Stanford Phase 1 clinical trial and whether they were achieved. In addition, please

disclose any observed serious adverse events.
Our tri-specific program, CRG-023, page 127

14. Please identify the referenced study published in June 2023.
Establishment of a commercial manufacturing process for CRG-022, page 138

15. We note your disclosure that the manufacturing process for CRG-022 builds upon the process used to manufacture CRG-022 used by Stanford. If your manufacturing process uses technology developed by Stanford, please indicate in an appropriate location whether such technology is in-licensed under the Stanford Agreement.
Competition, page 145

16. With respect to your disclosures regarding competitors, please explain the difference between autologous and allogenic CAR T therapies.
Intellectual Property, page 147

17. Please specify the foreign jurisdictions in which you have pending applications, licensed patents or licensed pending patents.

License Agreements, page 149

18. Please revise your Stanford Agreement and National Cancer Institute license agreement disclosures relating to "double-digit percentage" of milestone payments applicable to product covered by licensed patent rights on non-patented products, "low double-digit percentage" of non-royalty revenue in the event you choose to exercise your right to sublicense, and "low single-digit to a low double-digit percentage" to specify a percentage rate or range that does not exceed ten percentage points.

Notes to the Financial Statements for the year ended December 31, 2022

11. License and research and development agreements

Oxford license and supply agreement, page F-27

19. Please disaggregate the $9.3 million milestone payments you may be required to pay into development, regulatory and commercial milestones.

General

20. Please ensure the writing is legible in the visual depictions throughout your draft registration statement. For example only, your visual under Pre STASH technology on page 145 contains illegible text.

21. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or

not they retain copies of the communications.

You may contact Christine Torney at 202-551-3652 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

FirstName LastNameHalley Gilbert

Division of Corporation Finance

Comapany NameCARGO Therapeutics, Inc.

Office of Life Sciences

cc: Benjamin A. Potter, Esq.

FirstName LastName