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): October 6, 2022

Allogene Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38693**	**82-3562771**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

210 East Grand Avenue, South San Francisco, California 94080
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 457-2700
(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 (see General Instruction A.2. below):

- ☐ 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	**ALLO**	**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 8.01 Other Events.

On October 6, 2022, Allogene Therapeutics, Inc. ("we", "us" and "our") announced the initiation of the Phase 2 clinical trial of ALLO-501A ("ALPHA2 trial") in patients with relapsed/refractory large B-cell lymphoma ("r/r LBCL"). We are also in the process of initiating the EXPAND trial, which is intended to demonstrate the contribution of ALLO-647 to the lymphodepletion regimen.

We conducted an extensive Phase 1 program designed to evaluate and optimize all aspects of our therapy, including multiple doses and schedules of ALLO-501A and ALLO-647. In addition, we recently conducted a review of the Phase 1 program, which determined a manufacturing process associated with robust clinical performance. Our selected manufacturing process, named Alloy, will be deployed in the ALPHA2 and EXPAND trials.

We received chemistry, manufacturing and controls clearance from the United States Food and Drug Administration (the "FDA") to use newly manufactured product that did not utilize the Alloy process from our manufacturing facility, Cell Forge 1 ("CF1"). We are now in the process of implementing Alloy in CF1. As such, the Phase 2 trial will begin with previously manufactured material from our prior contract manufacturing organization ("CMO") with the intent of transitioning to product from CF1 during the course of the ALPHA2 and EXPAND trials.

The single-arm ALPHA2 trial will utilize a single dose of ALLO-501A at 120 million CAR+ cells with an intended lymphodepletion regimen comprised of fludarabine (30 mg/m2/day x 3 days) and cyclophosphamide (300 mg/m2/day x 3 days) plus ALLO-647 (90 mg). We plan to enroll approximately 100 patients who have received at least two prior lines of therapy and have not received any prior anti-CD19 therapy, including CAR T therapy. The primary endpoint is objective response rate.

The EXPAND trial is a separate potentially registrational trial for ALLO-647. ALLO-647 is an anti-CD52 monoclonal antibody that we are developing with the goal of potentially enabling expansion, persistence and improved clinical outcomes of allogeneic CAR T cell product candidates, including ALLO-501A. The randomized EXPAND trial is expected to enroll approximately 70 patients with r/r LBCL and is intended to demonstrate the safety of ALLO-647 and its contribution to the overall benefit of the lymphodepletion regimen. Patients will be randomized to receive the same single 120 million CAR+ cell dose of ALLO-501A as in the ALPHA2 trial and either lymphodepletion with fludarabine and cyclophosphamide (control arm) or the lymphodepletion regimen of the ALPHA2 trial (active arm).

Assuming favorable outcomes and subject to FDA discussions, we plan to seek FDA approval of ALLO-501A and ALLO-647 on the basis of the ALPHA2 trial and the EXPAND companion trial.

We expect to provide an update on our CD19 program toward the end of 2022. This will include longer-term follow-up from our Phase 1 ALPHA and ALPHA2 clinical trials, including patients treated with the Alloy manufacturing technology process.

The below risk factor supplements the risk factors described in Item 1A of our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022 ("Form 10-Q") and our Form 8-K filed on September 21, 2022 ("September Form 8-K"). The following risk factor should be read in conjunction with the risk factors described in our Form 10-Q and our September Form 8-K.

We may fail to advance the ALPHA2 and EXPAND trials or obtain approval for ALLO-501A or ALLO-647 due to challenges in manufacturing, FDA review, or patient enrollment and outcomes.

We decided to initiate the Phase 2 trial of ALLO-501A with material manufactured utilizing the Alloy process at our CMO, rather than material manufactured at CF1, and intend to subsequently transition the Alloy process to CF1 during the course of the Phase 2 trial. This approach remains subject to FDA review, and may ultimately result in increased costs and delays in conducting the ALPHA2 trial and EXPAND trial, submitting a Biologics License Application ("BLA") or gaining FDA approval of ALLO-501A. In addition, we may be unable to manufacture additional Alloy material at the CMO or transition the Alloy manufacturing process to our manufacturing facility for ALLO-501A as well as for our other product candidates, which could delay our clinical trials.

As we progress the ALPHA2 and EXPAND trials, we may face challenges in enrollment, such as due to excluding patients with certain disease characteristics and those that have received prior autologous CAR T therapies, which continue to gain adoption. Any Phase 2 results may also not be representative of Phase 1 results, which were based on limited patients. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect ongoing FDA feedback on our trials, and, even if we believe the results are sufficiently compelling for both the ALPHA2 trial and EXPAND trial, the FDA could ultimately require longer-term follow-up results, additional data from our clinical trials or additional trials that could delay or prevent our first BLA submission.

Cautionary Note on Forward-Looking Statements

This Form 8-K contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This Form 8-K may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the timing and ability to progress the ALPHA2 trial and initiate the EXPAND trial; whether either of the ALPHA2 or EXPAND trials will be pivotal or registrational; clinical outcomes, which may materially change as more patient data become available; the ability to have a CMO manufacture allogeneic CAR T cell product candidates for use in ongoing clinical trials; the ability to transition the Alloy manufacturing process to CF1 and the ability of CF1 to manufacture allogeneic CAR T cell products for ALPHA2, EXPAND or other clinical trials; and the potential benefits of the Alloy process and allogeneic CAR T cell products. Various factors may cause differences between our expectations and actual results as discussed in greater detail in our filings with the Securities and Exchange Commission, including without limitation in this Form 8-K, our September Form 8-K and our Form 10-Q. Any forward-looking statements that are made in this Form 8-K speak only as of the date hereof. We assume no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date hereof.

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.

ALLOGENE THERAPEUTICS, INC.

By: /s/ Eric Schmidt, Ph.D.
Eric Schmidt, Ph.D.
Chief Financial Officer

Dated: October 6, 2022