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): June 3, 2023

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 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 June 3, 2023, Allogene Therapeutics, Inc. (the "Company") presented long-term follow up data from the Phase 1 ALPHA/ALPHA2 trials of ALLO-501/501A in patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL) at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. These data will also be presented in a poster session at the European Hematology Association (EHA) Hybrid Congress on June 9, 2023.

The updated analysis of ALPHA/ALPHA2 examined data from 12 CAR T-naïve patients with r/r LBCL who received a single dose of ALLO-501/501A manufactured using the Alloy™ process following a lymphodepletion regimen (FCA90) comprised of fludarabine (30 mg/m^2/day x 3 days) and cyclophosphamide (300 mg/m^2/day x 3 days) plus ALLO-647 (30 mg/day x 3 days). The median time from enrollment to the start of therapy was three days and all 12 patients were followed through a minimum of six months (data cutoff April 20, 2023).

	Patients Treated with Phase 2 Regimen (n=12)
Overall Response Rate (ORR), n (%)	8 (67)
Complete Response Rate (CR), n (%)	7 (58)
6 Month Complete Response, n (%)	5 (42)

As of the data cutoff, 7 of 12 (58%) patients achieved a CR and five (42%) maintained a CR through Month 6. Of the five patients who were in CR at 6 months, four (80%) remained in CR. The fifth patient had disease progression at 24 months. The median duration of response was 23.1 months with three patients remaining in remission for over 24 months and the longest remaining in remission for over 31 months.

	All r/r CAR T naïve LBCL (N=33)		Patients Treated with Phase 2 Regimen (N=12)	
	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)
CRS	8 (24)	0	4 (33)	0
ICANS	0	0	0	0
Neurotoxicity	13 (39)	2 (6)	4 (33)	0
GvHD	0	0	0	0
IRR	16 (49)	3 (9)	8 (67)	0
Infection	19 (58)	5 (15)	8 (67)	1 (8)
Prolonged Gr3+ Cytopenia	—	4 (12)	—	2 (17)

A safety analysis of 33 CAR T-naïve LBCL patients receiving Alloy™ process ALLO-501/501A product candidates at any dose and lymphodepletion schedule, including the 12 patients treated with the Phase 2 regimen, was also conducted. Treatment was generally well tolerated with no incidences of Grade 3 or greater cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome or graft versus host disease. Cytopenias and infections were manageable and comparable to the experience with autologous CAR T cell therapies in patients with r/r LBCL.

The ALPHA/ALPHA2 Phase 1 trials were designed to assess the safety, tolerability, and preliminary efficacy at increasing dose levels of ALLO-501 and ALLO-501A, allogeneic CAR T cell product candidates that target CD19. In addition to exploring cell doses, these studies evaluated various doses of ALLO-647, the Company's proprietary lymphodepleting antibody designed to prevent premature rejection of AlloCAR T cells. The Company is currently enrolling the potentially pivotal Phase 2 ALPHA2 trial of ALLO-501A in LBCL and expects to complete enrollment in the first half of 2024.

Cautionary Note on Forward-Looking Statements

This report contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This report 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: ALPHA2 being a potentially pivotal trial; expected completion of enrollment in ALPHA2 in the first half of 2024; the

potential safety profile of the Company's Phase 2 lymphodepletion and cell dose regimen; and the potential benefits of the Alloy process and AlloCAR T product candidates. Various factors may cause material differences between the Company's expectations and actual results, including risks and uncertainties related to: the Company's product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; Phase 1 data from the Company's clinical trials is limited and may change as more patient data become available or may not be validated in any future or advanced clinical trial; the Company's ability to maintain intellectual property rights necessary for the continued development of its product candidates, including pursuant to its license agreements; the Company's product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval or limit their commercial potential; the extent to which COVID-19 adversely impacts the Company's business, including its clinical trials; the extent to which the U.S. Food and Drug Administration disagrees with the Company's clinical or regulatory plans, which could cause future delays to the Company's clinical trials or require additional clinical trials; the Company may encounter difficulties enrolling patients in its clinical trials; the Company may not be able to demonstrate the safety and efficacy of its product candidates in its clinical trials, which could prevent or delay regulatory approval and commercialization; challenges with manufacturing or optimizing manufacturing of the Company's product candidates; and the Company's ability to obtain additional financing to develop its product candidates and implement its operating plans. These and other risks are discussed in greater detail in the Company's filings with the Securities and Exchange Commission, including without limitation in its Form 10-Q filed for the quarter ended March 31, 2023. Any forward-looking statements that are made in this report speak only as of the date of this report. The Company assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this report.

Caution should be exercised regarding statements comparing autologous CAR T data. There are differences in the clinical trial design, patient populations, published data, follow-up times and the product candidates themselves, and the results from the clinical trials of autologous products may have no interpretative value on the Company's existing or future results.

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/ David Chang, M.D., Ph.D.
David Chang, M.D., Ph.D.
President, Chief Executive Officer

Dated: June 7, 2023