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 15, 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 15, 2023, Allogene Therapeutics, Inc. ("Allogene," the "Company," "our" or "we") presented updated data from the Phase 1 ALPHA/ALPHA2 trials of ALLO-501/501A in 33 CAR T naïve patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL) treated with the Alloy™ manufacturing process material across different CAR T dosing and lymphodepletion regimens. Earlier in June, data from the 12 patients, a subset of these 33 CAR T naïve patients, who received regimen being utilized in ongoing Phase 2 trials was presented at American Society of Clinical Oncology (ASCO) Annual Meeting.

The updated analysis (data cutoff April 20, 2023) of ALPHA/ALPHA2 examined data from all 33 CAR T-naïve patients with r/r LBCL who were treated with a single infusion or consolidation therapy (two planned infusions) of ALLO-501/501A manufactured using the Alloy™ manufacturing process. Patients received lymphodepletion with fludarabine (30 mg/m2/day x 3 days) and cyclophosphamide (300 mg/m2/day x 3 days) and varying doses of ALLO-647 (from 13 mg/day to 30 mg/day x 3 days).

The median time from enrollment to the start of therapy was three days and 100% of patients received product per specifications. No patients received bridging therapy. The dosing breakdown for the 33 patients included in this data set is as follows:

- 12 patients treated with a single dose of ALLO-501/501A and FCA90 lymphodepletion (Phase 2 regimen; recap of the ASCO 2023 data presentation)
- 6 patients treated with a single dose of ALLO-501/501A and FCA<90 lymphodepletion
- 15 patients treated with consolidation dosing of ALLO-501/501A and split lymphodepletion

	CAR T- Naïve Patients with r/r LBCL Alloy Manufacturing Process			
	All (N=33)	Phase 2 Regimen (N=12)	FCA<90 (N=6)	Consolidation Dosing (N=15)
Overall Response Rate (ORR), n (%)	19 (58)	8 (67)	3 (50)	8 (53)
Complete Response Rate (CR), n (%)	14 (42)	7 (58)	1 (17)	6 (40)
6 Month Complete Response, n (%)	10 (30)	5 (42)	0	5 (33)

Seven of 12 (58%) patients receiving the Phase 2 regimen 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. Across all 33 patients the CR rate was 42% with 30% maintaining a CR at Month 6. These results indicate complete responses are more common with lymphodepletion regimens containing 90 mg of ALLO-647 (FCA90). Median duration of response for both the overall population (n=33) and the patients treated with the Phase 2 regimen (n=12) was 23.1 months.

	CAR T- Naïve Patients with r/r LBCL							
	All (N=33)		Phase 2 Regimen (N=12)		FCA<90 (N=6)		Consolidation (N=15)	
	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)
CRS	8 (24)	0	4 (33)	0	1 (17)	0	3 (20)	0
Neurotoxicity	13 (39)	2 (6)	4 (33)	0	2 (33)	0	7 (47)	2 (13)
ICANS	0	0	0	0	0	0	0	0
GvHD	0	0	0	0	0	0	0	0
IRR	16 (49)	3 (9)	8 (67)	0	3 (50)	1 (17)	5 (33)	2 (13)
Infection	19 (58)	5 (15)	8 (67)	1 (8)	3 (50)	1 (17)	8 (53)	3 (20)
Prolonged Gr3+ Cytopenia	—	4 (12)	—	2 (17)	—	0	—	2 (13)

Across the 33 patients, 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. Cytopenia 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 multiple cell doses, these studies evaluated various doses of ALLO-647, Allogene's proprietary lymphodepleting antibody designed to prevent premature rejection of AlloCAR T cells. Allogene is currently enrolling the potentially pivotal Phase 2 ALPHA2 trial of ALLO-501A in LBCL and expects to complete enrollment in 1H2024. The Company expects to open trial sites in Europe, Canada and Australia during 2023.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as "could," "designed," "expects," "potential," "preliminary," "will" 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 potential of the Phase 2 ALPHA2 trial to be a pivotal trial; Allogene's expectation to complete enrollment of the Phase 2 ALPHA2 trial in the first half of 2024; Allogene's expectation to open trial sites for the Phase 2 ALPHA2 trial in Europe, Canada and Australia during 2023; the design of Allogene's trials and ALLO-647; data results that may be implied from prior results; and the potential benefits of AlloCAR T products. Various factors may cause material differences between Allogene's expectations and actual results, including, risks and uncertainties related to: our 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 our 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; our ability to maintain intellectual property rights necessary for the continued development of our product candidates, including pursuant to our license agreements; our 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 our business, including our clinical trials; the extent to which the FDA disagrees with our clinical or regulatory plans, which could cause future delays to our clinical trials or require additional clinical trials; we may encounter difficulties enrolling patients in our clinical trials; we may not be able to demonstrate the safety and efficacy of our product candidates in our clinical trials, which could prevent or delay regulatory approval and commercialization; challenges with manufacturing or optimizing manufacturing of our product candidates; and our ability to obtain additional financing to develop our products and implement our operating plans. These and other risks are discussed in greater detail in Allogene's filings with the SEC, including without limitation under the "Risk Factors" heading of its Form 10-Q for the quarter ended March 31, 2023. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Allogene 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 press release.

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 Allogene'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 21, 2023