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 7, 2021

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 October 7, 2021, Allogene Therapeutics, Inc. (the "Company") reported that, following a report of a chromosomal abnormality in ALLO-501A chimeric antigen receptor ("CAR") T cells in a patient treated in the ALPHA2 study, the U.S. Food and Drug Administration ("FDA") has placed a hold on the Company's clinical trials.

The clinical hold follows the Company's notification to the FDA of a chromosomal abnormality in an ALPHA2 study patient which was detected in a bone marrow biopsy undertaken to assess pancytopenia (low blood counts). An investigation is underway to further characterize the observed abnormality, including any clinical relevance, evidence of clonal expansion or potential relationship to gene editing. The Company expects to provide additional updates in the coming weeks following consultation with the FDA. The FDA continues to actively review the end of Phase 1 materials submitted in anticipation for an ALLO-501A pivotal Phase 2 trial.

The single case involves a patient with Stage IV transformed follicular lymphoma and a type of genetic rearrangement, known as c-myc rearrangement, whose cancer was refractory to two prior lines of immune-chemotherapy and additional radiation therapy. The patient could not receive an autologous anti-CD19 CAR T cell therapy due to manufacturing failure associated with inadequate expansion of autologous CAR T cells.

Following infusion of ALLO-501A, the patient experienced Grade 1 cytokine release syndrome and Grade 2 immune effector cell-associated neurotoxicity syndrome, which required a course of high dose steroid therapy. The patient subsequently developed progressive pancytopenia and a bone marrow biopsy showed aplastic anemia and the presence of ALLO-501A CAR T cells with the chromosomal abnormality. Early translational data showed that the CAR T cells expanded, peaking on Day 28, and undergoing contraction thereafter. The patient had a partial response to ALLO-501A and subsequently underwent allogeneic stem cell transplantation. Prolonged cytopenia requiring rescue stem cell transplantation has been reported in autologous CAR T therapies.

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: October 7, 2021