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): January 3, 2024

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 1.01 Entry into a Material Definitive Agreement.

On January 3, 2024, Allogene Therapeutics, Inc. (the "Company") entered into a Strategic Collaboration Agreement (the "Agreement") with Foresight Diagnostics, Inc. ("Foresight"). Pursuant to the Agreement, the parties have agreed to collaborate on a non-exclusive basis in the development of Foresight's minimal residual disease ("MRD") assay as an in vitro diagnostic to identify the MRD+ patient population to be enrolled in the Company's planned ALPHA3 trial of cemacabtagene ansegedleucel (formerly known as ALLO-501A), or cema-cel, for the treatment of large B cell lymphoma ("LBCL"), which trial is described in further detail under Item 8.01, below.

Under the Agreement, the Company has agreed to use its commercially reasonable efforts to obtain regulatory approval of cema-cel, and Foresight has agreed to use its commercially reasonable efforts to obtain regulatory approval of an MRD assay for use as an in vitro diagnostic with cema-cel. The Company has agreed to fund approximately $26 million in MRD assay development costs, milestone payments for regulatory submissions and assay utilization to process clinical samples.

Each party will retain ownership to their own background intellectual property and will own any improvements made to their respective intellectual property during the course of the collaboration.

Either party may terminate the Agreement (i) in the event of the other party's material breach, subject to a cure period, (ii) in the event of the other party's insolvency, and (iii) if a regulatory authority determines not to grant regulatory approval of cema-cel or Foresight's MRD assay for use as an in vitro diagnostic with cema-cel. In addition, the Company may terminate the Agreement for convenience upon advance notice to Foresight, subject to paying Foresight a termination payment associated with certain activities of Foresight.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On January 4, 2024, the Company's Board of Directors approved a reduction in the Company's workforce of approximately 22% of the Company's employees in connection with the Company's pipeline prioritization and clinical development strategy. The reduction in workforce is expected to be substantially completed by the end of January 2024.

The Company estimates that it will incur charges of approximately $5.0 million to $5.5 million for severance payments and employee benefits, primarily in the first quarter of 2024. Substantially all of the estimated charges are expected to result in future cash expenditures. The estimated charges that the Company expects to incur are subject to a number of assumptions, and actual results may differ materially from these estimates. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, its reduction in workforce.

Item 8.01 Other Events.

On January 4, 2024, the Company announced its intention to commence a Phase 2, pivotal clinical trial of cema-cel as part of the first line ("1L") treatment plan for newly diagnosed and treated LBCL patients who are likely to relapse and need further therapy (such trial, the "ALPHA3 trial"). The Company intends to initiate the ALPHA3 trial mid-2024. The trial design contemplates randomizing approximately 230 patients who are MRD+ at the end of 1L therapy to either consolidation with cema-cel or the current standard of care (observation). The design, with a primary endpoint of event free survival, includes two lymphodepletion arms: one with standard fludarabine and cyclophosphamide plus ALLO-647 and one without ALLO-647. The outcome of this pivotal trial could allow cema-cel to be embedded in the 1L setting to boost cure rates, potentially rendering later-line treatment obsolete, and making cema-cel available in community centers where most earlier line patients seek care.

Given the vision for cema-cel as part of 1L treatment, the Company expects the CD19 CAR T market in second line ("2L") and third line ("3L") could be significantly diminished. Accordingly, the Company plans to focus cema-cel clinical development resources into the ALPHA3 trial and deprioritize its currently enrolling 3L trials (ALPHA2 and EXPAND).

Forward-Looking Statements

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although the Company believes that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, the Company can give no assurance that such expectations and assumptions will prove to be correct. Forward-looking statements include all statements that are not historical facts and can generally be identified by terms such as "could," "estimate," "expect," "intend," "may," "plan," "potentially," or "will" or similar expressions and the negatives of those terms. These statements include, but are not limited to, statements regarding the expectations related to the costs, timing, and estimated financial impacts of the reduction in workforce, including the estimated expenditures associated with the reduction in

workforce, other statements related to the planned reduction in workforce, statements related to the planned ALPHA3 trial, including it being a pivotal trial, and the potential outcome of the trial, statements related to the CD19 CAR T market and the Company's other clinical programs, activities to be performed under the Agreement with Foresight and the outcome of such activities, and other statements relating to future events or conditions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors relate to, among others: the Company's ability to successfully implement the reduction in workforce; the actual charges in implementing the reduction in workforce; changes to the assumptions on the estimated charges associated with the reduction in workforce; unintended consequences from the reduction in workforce; changes in the macroeconomic environment or industry that impact the Company's business; competition; risks related to third-party performance; 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; Servier's discontinuation of its involvement in the development of all CD19 products pursuant to the Company's Exclusive License and Collaboration Agreement and the Company's disputes with Servier may have adverse consequences; the limited nature of the Phase 1 data from the Company's clinical trials and the extent to which such data may or may not be validated in any future 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 the Food and Drug Administration disagrees with the Company's clinical or regulatory plans or the import of the Company's clinical results, 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, including the ALPHA3 trial; there is no guarantee that Foresight will successfully develop an MRD assay for use as an in vitro diagnostic with cema-cel, and without an in vitro diagnostic the prospects for cema-cel could be materially and negatively impacted; 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 or any in vitro diagnostic for use with 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 factors are described in greater detail under the "Risk Factors" heading of the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on November 2, 2023. All information provided in this report is as of the date of this report, and any forward-looking statements contained herein are based on assumptions that the Company believes to be reasonable as of this date. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. The Company undertakes no duty to update this information unless required by law.

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: January 5, 2024