
**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): May 13, 2025

Allogene Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38693
(Commission
File Number)

82-3562771
(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. of Form 8-K):

- 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 2.02 Results of Operations and Financial Condition.

On May 13, 2025, Allogene Therapeutics, Inc. (the “Company”) provided a corporate update and announced its financial results for the quarter ended March 31, 2025 in the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

**Exhibit
Number****Description**

99.1	Press Release of the Company, dated May 13, 2025.
104	The cover page of this report has been formatted in Inline XBRL.

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: May 13, 2025



Allogene Therapeutics Reports First Quarter 2025 Financial Results and Business Update

- **Pivotal Phase 2 ALPHA3 Trial with Cemacabtagene Ansedgleucl (Cema-Cel) in First-Line (1L) Consolidation in Large B-Cell Lymphoma (LBCL)**
 - Nearly 50 Sites Activated Across U.S. with Strong Enthusiasm from Investigators
 - Lymphodepletion Selection and Futility Analysis Shifted to 1H 2026 in Part Due to Site-Related Factors that Impacted Expected Pace of Screening Immediately Following Site Activation
 - Over 250 Patients Consented for MRD Screening to Date, with Nearly Half in the Last Three Months and Awaiting Completion of 1L Treatment as Earliest Activated Sites Build Momentum
 - International Expansion of ALPHA3 Trial to Begin with Site Activations in Canada in Q2 2025
- **Phase 1 RESOLUTION Trial with ALLO-329 in Autoimmune Disease (AID)**
 - RESOLUTION Basket Trial in Rheumatology on Track for Mid-2025 Start
 - Proof-of-Concept Data Moved to 1H 2026 to Enable Inclusion of Both Biomarker and Clinical Data
- **Phase 1 TRAVERSE Trial with ALLO-316 in Renal Cell Carcinoma (RCC)**
 - Updated Phase 1 Trial Results Will be Featured in an Oral Presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting
 - Presentation to Highlight Meaningful Clinical Responses from the Phase 1B Expansion Cohort and Key Translational Findings, Including Ability for CD70 Dagger® Technology to Drive Robust CAR T Cell Expansion and Persistence
- Ended Q1 2025 with \$335.5 Million in Cash, Cash Equivalents and Investments
 - Cost Realignment and Strategic Prioritization Will Extend Cash Runway Into 2H 2027
 - Spend Focused on Advancing the Cema-Cel/ALPHA3 and ALLO-329/RESOLUTION Clinical Trials to Key Inflection Points
 - Targeted Reductions in Manufacturing Operations Provide Key Savings While Preserving Core Capabilities
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., May 13, 2025 – Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer and autoimmune disease, today provided corporate updates and reported financial results for the quarter ended March 31, 2025.

“We are executing on a strategy that is grounded in science, shaped by real-world insights, and supported by a platform purpose-built to scale,” said David Chang, M.D., Ph.D., President, Chief Executive Officer, and Co-Founder of Allogene. “From transforming the role of CAR T in first-line LBCL through ALPHA3 to breaking new ground in autoimmune disease with ALLO-329 to showing what’s possible in solid tumors with ALLO-316, we are leading where others have yet to go. The experience we’ve gained from our trials, the commitment from our partners, and the unmatched efficiencies of our allogeneic platform reinforce my confidence that our approach is not only working but also defining the future of cell therapy. We have never been clearer about our path or more certain about the value we can deliver to patients and the field.”

Program Updates

Cema-Cel: Pivotal Phase 2 ALPHA3 1L Consolidation Trial in LBCL

The ALPHA3 trial evaluating cema-cel as 1L consolidation therapy for LBCL remains a cornerstone of Allogene’s clinical strategy. The trial now includes nearly 50 activated sites across the U.S., spanning both community cancer centers and leading academic institutions. The trial uniquely identifies high-risk patients using Foresight CLARITY™ powered by PhasED-Seq™, an Investigational Use Only (IUO) MRD test, and randomizes approximately 240 patients to assess whether early intervention with cema-cel improves event-free survival (EFS) compared to observation, which is the current standard of care.

As the first study of its kind, ALPHA3 has delivered valuable real-world insights. Since launching in mid-2024, Allogene has partnered closely with sites to refine patient identification strategies; educated patients on their relapse risk and opportunity for additional therapy based on MRD status; and navigated expected and unforeseen challenges. Chief among these has been industry-wide factors that have delayed site readiness to initiate screening activities for three months or more after activation. As a result, the milestone for lymphodepletion regimen selection and futility analysis has been shifted by approximately two quarters and is now expected in the first half of 2026.

The momentum behind ALPHA3 however has been tangible and significant, driven by a strong partnership between Allogene and its clinical sites. Several sites have proactively collaborated with the Company to develop and share best practices, fostering a coordinated network. An important measure of success is the identification of patients early in 1L treatment who are interested in the trial and consenting them for MRD testing at completion of therapy. This metric is now being consistently met as earlier introduction to the trial has increased the proportion of screening-eligible patients advancing to MRD testing and, if positive, agreeing to randomization. With the earliest activated sites now screening regularly and newly activated sites implementing best practices immediately, we have now consented over 250 patients for MRD screening, with nearly half of these consents occurring in the last three months. Meanwhile, growing international interest has prompted expansion of the trial footprint outside the U.S., a move expected to accelerate enrollment further and strengthen trial execution.

The Company will intentionally hold off on projecting additional milestones until after the first milestone for lymphodepletion regimen selection and futility analysis. Recognizing the strategic significance of this inflection point and guided by stakeholder feedback, the Company is re-evaluating what data will be appropriate to share at the time of the lymphodepletion announcement.

ALLO-329: CD19/CD70 Dual CAR with Dagger® Technology in AID

ALLO-329 offers a novel approach to treating autoimmune diseases as the first allogeneic CD19/CD70 dual CAR T product specifically designed to target CD19+ B-cells and CD70+ activated T-cells, both of which are key players in autoimmune diseases. The investigational product utilizes CRISPR-based site-specific integration and incorporates the Company's clinically validated Dagger® technology, which aims to reduce or eliminate the need for lymphodepletion, believed to be a potentially significant obstacle to the broader adoption of CAR T therapies in autoimmune indications.

The Phase 1 RESOLUTION basket trial in rheumatology will begin in mid-2025. The trial will include patients with systemic lupus erythematosus, including lupus nephritis, idiopathic inflammatory myopathies, and systemic sclerosis. The innovative design of the RESOLUTION trial will include two distinct lymphodepletion arms: one using a dose of cyclophosphamide alone and another that eliminates lymphodepletion entirely. The Company has shifted timing for its first update to this program to 1H 2026 to allow for both biomarker and clinical proof-of-concept data.

ALLO-316: TRAVERSE Trial in RCC

ALLO-316 is the only allogeneic CAR T therapy to show potential in solid tumors. Enrollment has completed in the Phase 1b cohort, which is evaluating the safety and efficacy of ALLO-316 at DL2 (80M CAR T cells) in patients with heavily pretreated advanced or metastatic RCC. The Company will present updated data from the Phase 1b cohort in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2025, in Chicago, Illinois.

2025 First Quarter Financial Results

- Research and development expenses were \$50.2 million for the first quarter of 2025, which includes \$5.0 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$15.0 million for the first quarter of 2025, which includes \$7.1 million of non-cash stock-based compensation expense.
- Net loss for the first quarter of 2025 was \$59.7 million, or \$0.28 per share, including non-cash stock-based compensation expense of \$12.2 million.
- The Company had \$335.5 million in cash, cash equivalents, and investments as of March 31, 2025.

In recognition of the evolving macroeconomic environment and the importance of preserving capital, the Company has taken steps to optimize its operations and extend the financial runway. Strategic cost-realignment efforts have been implemented to prioritize high-impact, value-generating program which include the clinical advancement of cema-cel in the ALPHA3 trial and ALLO-329 in the RESOLUTION trial. Operational savings have been achieved through a tactical reduction in manufacturing operations, leveraging prior infrastructure investments and the inherent efficiencies of the Company's allogeneic CAR T platform, while preserving core capabilities. These actions have extended the cash runway into the second half of 2027, allowing the Company to strengthen its ability to weather market uncertainty as it executes clinical programs through key milestones. As a result of these efforts, new guidance for 2025 is an expected decrease in cash, cash equivalents, and investments of approximately \$150 million. GAAP Operating Expenses are now expected to be approximately \$230 million, including estimated non-cash stock-based compensation expense of approximately \$45 million. These estimates exclude any impact from potential business development activities.

Conference Call and Webcast Details

Allogene will host a live conference call and webcast today at 2:00 p.m. PT / 5:00 p.m. ET to discuss financial results and provide a business update. If you would like the option to ask a question on the conference call, please use this link to register. Upon registering for the conference call, you will receive a personal PIN to access the call, which will identify you as the participant and allow you the option to ask a question. The listen-only webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About Allogene Therapeutics

Allogene Therapeutics, with headquarters in South San Francisco, is a clinical-stage biotechnology company pioneering the development of allogeneic chimeric antigen receptor T cell (AlloCAR T™) products for cancer and autoimmune disease. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of “off-the-shelf” CAR T cell product candidates with the goal of delivering readily available cell therapy on-demand, more reliably, and at greater scale to more patients. For more information, please visit www.allogene.com, and follow Allogene Therapeutics on X and LinkedIn.

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 “expected,” “awaiting,” “projected,” “potential,” “targeted,” “believes,” “will,” “aims to,” “scheduled to,” “drive,” “guidance,” “estimated,” “advancing,” “may,” “could,” “designed to,” “defining,” “can,” “accelerate,” 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: ALPHA3 being a pivotal trial and the extent to which it will support regulatory approval of cema-cel; that ALPHA3 could transform the role of CAR T in first line LBCL; the potential for an investigational MRD test to identify high-risk patients and for cema-cel as a 1L consolidation therapy for LBCL; the potential that early intervention with cema-cel can improve event-free survival compared to standard of care observation; the ability to expand the ALPHA3 trial footprint outside of the U.S.; that expanding the trial footprint outside the U.S., refining patient identification strategies, earlier patient engagement, educating patients on their relapse risk, and/or strengthening partnerships with sites will lead to greater success in identifying patients, accelerating enrollment, and strengthening trial execution on the ALPHA3 trial; that ALLO-329 offers a novel approach and can break new ground in treating autoimmune disease; the ability for a dual-targeted CD19/CD70 allogeneic CAR T to safely and effectively treat a range of autoimmune indications; the ability for our Dagger technology in ALLO-329 to reduce or eliminate the need for lymphodepletion and induce broader adoption of CAR T therapies in autoimmune indications; the potential for ALLO-329 and the RESOLUTION trial to treat patients with systemic lupus erythematosus, including lupus nephritis, idiopathic inflammatory myopathies, and systemic sclerosis; the potential for ALLO-316 to safely and effectively treat patients with advanced or metastatic RCC; the ability for CD70 Dagger technology to drive robust CAR T cell expansion and persistence; that the data and results from our Phase 1B TRAVERSE trial can be validated in future trials; the potential for our product candidates to safely treat cancer or autoimmune diseases, including as an “off-the-shelf” product; the pace, timing and extent to which we may initiate or enroll patients in our clinical trials or release data from such trials including ALPHA3, RESOLUTION, and TRAVERSE trials; our projected financial position, our expectation that our cash runway extends into the second half of 2027; financial guidance for 2025; and other statements related to future events or conditions. 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; the limited nature of our pre-clinical and Phase 1 data and the extent to which such data may or may not be validated in any future clinical trial; 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 the Food and Drug Administration disagrees with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials, including initiation of 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; and the challenges with manufacturing or optimizing manufacturing of our product candidates. These and other risks are discussed in greater detail in Allogene’s filings with the Securities and Exchange Commission (SEC), including without limitation under the “Risk Factors” heading in its Annual Report on Form 10-Q for the quarter ended March 31, 2025, being filed with the SEC today. 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.

AlloCAR T™ and Dagger® are trademarks of Allogene Therapeutics, Inc.
CLARITY™ and PhasED-Seq™ are trademarks of Foresight Diagnostics.

Allogene’s investigational AlloCAR T™ oncology products utilize Collectis technologies. The anti-CD19 oncology products are developed based on an exclusive license granted by Collectis to Servier. Servier, which has an exclusive license to the anti-CD19 AlloCAR T investigational products from Collectis, has granted Allogene exclusive rights to these products in the U.S., all EU Member States and the United Kingdom. The anti-CD70 AlloCAR T program is licensed exclusively from Collectis by Allogene and Allogene holds global development and commercial rights to this AlloCAR T program. ALLO-329 (CD19/CD70) in autoimmune disease uses CRISPR gene-editing technology.

ALLOGENE THERAPEUTICS, INC.**SELECTED FINANCIAL DATA**

(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2025	2024
Collaboration revenue - related party	\$ —	\$ 22
Operating expenses:		
Research and development	\$ 50,200	\$ 52,259
General and administrative	14,991	17,267
Total operating expenses	65,191	69,526
Loss from operations	(65,191)	(69,504)
Other income (expense), net:		
Interest and other income, net	5,516	5,433
Interest expense	(150)	—
Other income (expenses), net	92	(929)
Total other income (expense), net	5,458	4,504
Net loss	\$ (59,733)	\$ (65,000)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.38)
Weighted-average number of shares used in computing net loss per share, basic and diluted	215,358,619	169,128,362

SELECTED BALANCE SHEET DATA

	As of March 31, 2025	As of December 31, 2024
Cash, cash equivalents and investments	\$ 335,549	\$ 373,149
Total assets	507,982	548,710
Total liabilities	122,589	126,531
Total stockholders' equity	385,393	422,179

Allogene Media/Investor Contact:

Christine Cassiano

EVP, Chief Corporate Affairs & Brand Strategy Officer

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