Allogene Therapeutics Reports Third Quarter 2025 Financial Results and Business Update

Nov 6, 2025 at 4:05 PM EST

- **Pivotal Phase 2 ALPHA3 Trial with Cemacabtagene Ansegedleucel (Cema-Cel) in First Line (1L) Consolidation in Large B-Cell Lymphoma (LBCL)**
  - ALPHA3 Positions Company at the Forefront of MRD-guided, Earlier-Line Oncology Treatment
  - Additional Sites in Australia and South Korea Expected to Open in early 2026
  - Scheduled Futility Analysis, Focused on MRD Conversion Between Study Arms, on Track for 1H 2026
- **Phase 1 RESOLUTION Trial with ALLO-329 in Autoimmune Disease (AID)**
  - ALLO-329, a Dual CD19/CD70 CAR, Harnesses the Dagger® Technology to Reduce or Eliminate Lymphodepletion
  - RESOLUTION Basket Trial in Rheumatology Enrolling with Proof-of-Concept Data Planned for 1H 2026
- **Phase 1 TRAVERSE Trial with ALLO-316 in Renal Cell Carcinoma (RCC)**
  - ALLO-316 Achieves Durable Responses in RCC Representing a Potential Breakthrough for CAR T in Solid Tumors; Plans Ongoing to Determine the Next Phase of the Program
- Ended Q3 2025 with $277.1 Million in Cash, Cash Equivalents and Investments; Cash Runway Continued to be Projected Into 2H 2027
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2025 (GLOBE NEWSWIRE) -- 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 September 30, 2025. The Company continues to advance a portfolio that seeks to redefine access to cell therapy, bringing the power of CAR T earlier in disease, more reliably, and across a broader range of treatment settings.

“With our unique allogeneic approach to CAR T, the field has the ability to shift from highly personalized, patient-specific therapies to a new era of readily available, off-the-shelf treatments that can reach more patients earlier in their disease and wherever they receive care,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Having treated hundreds of patients, we’ve gained valuable insight into how ex vivo manufacturing enables more precise definition and control of our cell products before they reach patients, enhancing consistency, safety, and quality. This transformation is evident and goes far beyond incremental progress, it begins to establish a scalable allogeneic CAR T paradigm built to reach more patients, expand into broader care settings, and unlock the full potential of cell therapy.”

Cema-Cel: Pivotal Phase 2 ALPHA3 1L Consolidation Trial in LBCL
The pivotal Phase 2 ALPHA3 trial with cema-cel is pioneering the use of allogeneic CAR T therapy in earlier-line treatment of LBCL, an approach that could expand access for patients before disease progression and simplify delivery across community and academic centers. By leveraging minimal residual disease (MRD) as a guide for treatment intervention, a rapidly emerging focus across oncology, the ALPHA3 trial aims to position Allogene at the forefront of a transformative shift toward earlier, more precise, treatment. More than 50 clinical sites are active across the United States and Canada, spanning both community cancer centers and leading academic institutions. Additional sites in Australia and South Korea are progressing toward activation and are expected to open in early 2026.

The next milestone will be the futility analysis comparing MRD conversion between the two arms comparing cema-cel after standard fludarabine and cyclophosphamide (FC) lymphodepletion versus observation, expected in the first half of 2026. At that time, the Company plans to share MRD conversion rates from the randomized portion of the study.

ALLO-329: CD19/CD70 Dual CAR with Dagger® Technology in AID
The Phase 1 RESOLUTION trial with ALLO-329, a dual CD19/CD70 CAR incorporating Dagger® technology, is enrolling in a basket trial across multiple autoimmune conditions, including systemic lupus erythematosus (with or without lupus nephritis), idiopathic inflammatory myopathies, and systemic sclerosis. In this dose-escalation study, two treatment regimens are being explored: one with reduced intensity cyclophosphamide-only lymphodepletion, and the other with no lymphodepletion at all, a potential breakthrough for improving tolerability and enabling treatment in a broader patient population.

With its built-in lymphodepletion coming from the Dagger® technology as well as its ability to target both B cells and activated T cells, key drivers of autoimmune pathology, ALLO-329 represents one of the first to investigate how allogeneic CAR T could be uniquely suited to treat autoimmune disease at scale, with reduced or without lymphodepletion to facilitate a broader CAR T adoption in autoimmune indications. The first clinical update, expected in 1H 2026, will include biomarker data and clinical proof-of-concept data.

ALLO-316: TRAVERSE Trial in RCC
ALLO-316 remains the only allogeneic CAR T therapy to show clinically significant response rates and meaningful durability of response in a metastatic solid tumor. The TRAVERSE trial in renal cell carcinoma has completed enrollment in its Phase 1b cohort, evaluating ALLO-316 in heavily pretreated patients. Updated data presented at the 2025 ASCO Annual Meeting demonstrated early signs of efficacy and tolerability.

2025 Third Quarter Financial Results

- Research and development expenses were $31.2 million for the third quarter of 2025, which includes $2.8 million of non-cash stock-based compensation expense.
- General and administrative expenses were $13.7 million for the third quarter of 2025, which includes $5.9 million of non-cash stock-based compensation expense.
- Net loss for the third quarter of 2025 was $41.4 million, or $0.19 per share, including non-cash stock-based compensation expense of $8.7 million.
- The Company had $277.1 million in cash, cash equivalents, and investments as of September 30, 2025.

The Company continues to expect its cash runway to extend into the second half of 2027. Guidance for 2025 is an expected decrease in cash, cash equivalents, and investments of approximately $150 million. GAAP Operating Expenses are 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 within the meaning of the Private Securities Litigation Reform Act of 1995. This press release may, in some cases, use terms such as “expect,” “project,” “plan,” “scheduled,” “on track,” “aim,” “will,” “may,” “could,” “guidance,” “estimate,” “can,” and “potential,” and similar expressions 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: market trends, including any shift toward certain therapies; the markets for our product candidates, including redefining access to cell therapy, expanding CAR T into new therapeutic settings, and our ability to reach more patients, expand into broader care settings, or simplify CAR T delivery; our ability to control ex vivo manufacturing and consistently produce product meeting safety and quality standards; our position at the forefront of a transformative shift toward earlier, more precise treatment; the design, timing, and potential regulatory implications of the ALPHA3 trial of cema-cel (including futility analysis, MRD conversion readouts, and anticipated site activations); the RESOLUTION trial of ALLO-329 (including biomarker and proof-of-concept timing and the potential to reduce or eliminate lymphodepletion); the TRAVERSE program for ALLO-316; the potential benefits and scalability of our allogeneic CAR T and Dagger® technologies; and our financial outlook, including cash runway into the second half of 2027 and 2025 operating expense and cash usage guidance. Various factors may cause material differences between Allogene’s expectations and actual results, including risks and uncertainties related to: clinical development risks, including our novel allogeneic CAR T approach and the unproven first-line consolidation setting in LBCL, the possibility that early or Phase 1 data may not predict later outcomes, trial delays or enrollment challenges, and adverse events (including those previously observed in certain ALPHA3 arms); regulatory risks, including potential FDA or foreign authority disagreement with plans or interpretations, requests for additional data or trials, and possible requirements related to MRD assays; manufacturing and CMC risks, including challenges in consistent, scalable manufacturing and technology implementation that could affect timelines, outcomes, or availability; reliance on third parties, including licensors and collaborators (e.g., Cellectis, Servier, and Foresight Diagnostics); and financial risks relating to continued operating losses, the need for additional financing, and the possibility of not meeting financial guidance. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, being filed with the SEC today. Any forward-looking statements made in this press release speak only as of the date of this press release. Allogene assumes no obligation to update 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.

Allogene’s investigational AlloCAR T ™ oncology products utilize Cellectis technologies. The anti-CD19 oncology products are developed based on an exclusive license granted by Cellectis to Servier. Servier, which has an exclusive license to the anti-CD19 AlloCAR T investigational products from Cellectis, 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 Cellectis 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 September 30,	
	2025	**2024**
Operating expenses:		
Research and development	$ 31,164	$ 44,713

General and administrative	13,737	16,333
Impairment of long-lived assets	—	10,728
Total operating expenses	44,901	71,774
Loss from operations	(44,901)	(71,774)
Other income (expense), net:		
Interest and other income, net	3,926	6,705
Interest expense	(344)	(100)
Other income (expenses), net	(81)	(1,124)
Total other income (expense), net	3,501	5,481
Net loss	$ (41,400)	$ (66,293)
Net loss per share, basic and diluted	$ (0.19)	$ (0.32)
Weighted-average number of shares used in computing net loss per share, basic and diluted	222,038,680	209,188,551

SELECTED BALANCE SHEET DATA

	As of September 30, 2025	As of December 31, 2024
Cash, cash equivalents and investments	$ 277,138	$ 373,149
Total assets	439,771	548,710
Total liabilities	124,442	126,531
Total stockholders' equity	315,329	422,179

Allogene Media/Investor Contact:
Christine Cassiano
EVP, Chief Corporate Affairs & Brand Strategy Officer
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.