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): February 28, 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 Global Select Market**

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 February 28, 2023, Allogene Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the fourth quarter and year ended December 31, 2022 in the press release attached hereto as Exhibit 99.1 and 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) Exhibits

Exhibit Number	Description
99.1	Press Release of the Company, dated February 28, 2023.

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: February 28, 2023

Exhibit 99.1

Allogene Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

- Initiated Industry's First Potentially Pivotal Phase 2 Allogeneic CAR T Trial, ALPHA2, in Relapsed/Refractory (R/R) Large B Cell Lymphoma (LBCL)
- Presented Data Highlighting Industry-Leading Allogeneic CAR T Portfolio
  - CD19 (ALLO-501/A): Six Month Durability and Progression Free Survival in R/R LBCL Comparable with Approved Autologous CAR T Therapies
  - BCMA (ALLO-715): First Allogeneic CAR T to Demonstrate Deep and Durable Responses in R/R Multiple Myeloma (MM)
  - CD70 (ALLO-316): Initial Proof-of-Concept for an Allogeneic CAR T in Solid Tumors
- Published Phase 1 Data from the UNIVERSAL Study of ALLO-715 in *Nature Medicine*
- Presented Dagger™ Technology, a Next Generation Allogeneic Platform Designed to Control Rejection of AlloCAR T Cells
- Ended 2022 with $576 Million in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., February 28, 2023 – Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today provided a corporate update and reported financial results for the quarter and year ended December 31, 2022.

"We are very proud that data from our pipeline candidates continues to break new ground in the field of allogeneic cell therapy. From our CD19 program for non-Hodgkin lymphoma to our BCMA program for multiple myeloma, we have established that our AlloCAR T technology can induce deep, clinically meaningful responses in patients," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "We continue to hear from physicians that gaining access to autologous CAR T therapy and the inevitable wait times associated with manufacturing remain a critical factor for patients. We believe the future of CAR T rests on the ability for an off-the-shelf option to address both time and access. The data we presented at our R&D Showcase in late 2022 indicates Allogene is making large strides toward giving patients back precious time."

Pipeline Updates

ALLO-501A: Anti-CD19 AlloCAR T Program
In October 2022, Allogene initiated the industry's first potentially pivotal Phase 2 allogeneic CAR T clinical trial with ALLO-501A. The single-arm trial is enrolling patients with relapsed/refractory (r/r) large B cell lymphoma (LBCL) and utilizes a single dose of ALLO-501A (120 million CAR+ cells) with the FCA90 (fludarabine, 30mg/m2, cyclophosphamide 300 mg/m2 and ALLO-647 30 mg, daily for 3 days) lymphodepletion regimen. The ALPHA2 trial will enroll approximately 100 patients who have received at least two prior lines of therapy and have not received prior anti-CD19 therapy. The primary endpoint of this trial is overall response rate (ORR), and the key secondary endpoint is duration of response (DoR). Patients may receive treatment as an outpatient at the investigator's discretion. The Company expects to complete enrollment in the Phase 2 ALPHA2 trial in 1H 2024.

In November 2022, Phase 1 data from the ALPHA trial with ALLO-501 and ALPHA2 trial with ALLO-501A for the treatment of r/r LBCL was presented at the Company's R&D Showcase. Data from the Phase 1 trials of ALLO-501 and ALLO-501A support the ability of a single administration of CAR T cells to generate deep and durable responses comparable to those with approved autologous CAR T therapies. Highlights included:

- As of the October 25, 2022 data cutoff, the ORR and Complete Response (CR) rate was 67% and 58%, respectively, among the 12 patients treated with the Single Dose FCA90 regimen using Alloy™ process material. The median duration of response was 23.1 months.
- Of patients who received single dose FCA90 and evaluable at six months, the ongoing CR rate was 50% and all CRs at six months were durable at 12 months. The longest CR ongoing at 26+ months.
- Phase 1 trials demonstrated a manageable safety profile with no observed dose limiting toxicities (DLTs), graft-vs-host disease (GvHD) or severe immune effector cell-associated neurotoxicity syndrome (ICANS).
- Among patients treated with Single Dose FCA90, there was no Grade 3+ cytokine release syndrome (CRS). One patient (8%) experienced a Grade 3+ infection and two (17%) experienced prolonged Grade 3+ cytopenia.

- 92% of all enrolled patients received product with 100% of infused product manufactured and released per product specifications. Patients were able to initiate treatment within two days of enrollment.

The Company is preparing for a Phase 3 study in earlier line LBCL targeting trial initiation in 1H 2024.

The Company is developing ALLO-647, its proprietary anti-CD52 monoclonal antibody intended to enable expansion and persistence of AlloCAR T product candidates, including ALLO-501A. The EXPAND trial, which is intended to demonstrate the contribution of ALLO-647 to the lymphodepletion regimen, will be open to enrollment early in the second quarter.

ALLO-715: Anti-BCMA AlloCAR T Programs
Data from the Phase 1 UNIVERSAL trial with ALLO-715 for the treatment of r/r multiple myeloma (MM) was also presented at the Company's R&D Showcase and subsequently published in *Nature Medicine*, accompanied by an editorial. The UNIVERSAL trial is the first allogeneic anti-BCMA CAR T to demonstrate proof-of-concept in MM with response rates that are similar to an approved autologous CAR T therapy. Highlights include:

- Dose expansion cohorts demonstrated substantial and durable responses.
- Through a median follow-up of 14.8 months as of the October 11, 2022 data cutoff, the ORR was 67% in the FCA60 cohort and the very good partial response or better rate (VGPR+) was 42%. All VGPR+ were minimal residual disease (MRD) negative.
- The median DoR was 9.2 months, with the longest response ongoing at 24 months.
- 92% of all enrolled patients received product with 100% of infused product manufactured and released as per product specifications. None of the patients received bridging therapy and patients were able to initiate treatment immediately following enrollment. Median time from enrollment to lymphodepletion was 5 days.
- Safety profile was manageable with low-grade and reversible neurotoxicity and no GvHD. Eight patients (29%) experienced Grade 3+ infections and eight patients experienced prolonged Grade 3+ cytopenias.

The Company is evaluating manufacturing processes improvements across its BCMA candidates to achieve optimal performance.

ALLO-316: Anti-CD70 AlloCAR T Program
ALLO-316, the Company's first AlloCAR T candidate for solid tumors, targets CD70, an antigen expressed on clear cell renal cell carcinoma (RCC) and other malignancies. At the Company's R&D Showcase, the Company presented initial data demonstrating promising anti-cancer activity in the subset of nine patients with confirmed CD70-positive RCC from the ongoing Phase 1 TRAVERSE trial. Highlights include:

- As of the data cutoff date of November 17, 2022, the disease control rate (DCR) in patients who were CD70+ was 100% including three patients who achieved a partial response (PR) (two confirmed and one unconfirmed with the longest response lasting until month eight).
- Cell expansion in patients with CD70 positive tumor was robust, and there was a trend toward greater tumor shrinkage in patients with high CD70 expression.
- Across all patients treated in the trial, ALLO-316 has demonstrated a generally manageable safety profile with no GvHD. One dose limiting toxicity of auto-immune hepatitis occurred in the second dose level. Grade 3+ prolonged cytopenia was observed in three patients (18%). Grade 3 CRS was observed in one patient. Neurotoxicity was low grade, reversible and seen in only three patients (18%).

The Company is deploying a new investigational in vitro companion diagnostic (IVD) assay designed to prospectively assess CD70 expression levels to enhance patient selection. TRAVERSE will continue to explore varying cell dose and lymphodepletion regimens, including FC and FCA. Subject to ongoing results in the TRAVERSE trial, the Company intends to complete planned dose exploration and initiate expansion cohort enrollment in 2023. The Company may also investigate ALLO-316 for other CD70 expressing solid tumors and hematologic indications, or in combination with other anticancer therapies such as immune checkpoint inhibitors.

Next Generation Platform Technology
Allogene has pursued an integrated strategy within Research and Development aimed at matching technology with insights obtained from the clinic to create solutions designed to advance patient outcomes. One of these is Dagger™, a proprietary technology designed to control rejection of AlloCAR T cells by the host immune cells. This technology deploys a CD70 CAR on AlloCAR T cells in an effort to recognize and deplete CD70 positive alloreactive host T cells. Preclinical data indicate that CD70 Dagger CARs can be combined with other anti-tumor CARs in a single cell, providing both protection from allorejection and dual specificity killing capability, thus offering a differentiated next generation product candidate profile.

Fourth Quarter and Year-End Financial Results

- Research and development expenses were $75.4 million for the fourth quarter of 2022, which includes $7.4 million of non-cash stock-based compensation expense. For the full year of 2022, research and development expenses were

$256.4 million. Research and development expense for the year includes $42.5 million of non-cash stock-based compensation expense.

- General and administrative expenses were $21.0 million for the fourth quarter of 2022, which includes $9.8 million of non-cash stock-based compensation expense. For the full year of 2022, general and administrative expenses were $79.3 million, which includes $41.1 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2022 was $94.8 million, or $0.66 per share, including non-cash stock-based compensation expense of $17.2 million. For the full year of 2022, net loss was $332.6 million, or $2.32 per share, including non-cash stock-based compensation expense of $83.6 million.
- The Company had $576.5 million in cash, cash equivalents, and investments as of December 31, 2022.

2023 Financial Guidance

- The Company expects a decrease in cash, cash equivalents, and investments of approximately $250 million in 2023. Based on current expectation, the Company expects the cash runway to be sufficient to fund operations into 2025. GAAP Operating Expenses are expected to be approximately $350 million, including estimated non-cash stock-based compensation expense of approximately $90 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. Pacific Time / 5:00 p.m. Eastern Time 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. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of “off-the-shelf” CAR T cell 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 @AllogeneTx on Twitter 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 "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" 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 timing and ability to progress the ALPHA2 and TRAVERSE trials; the timing and ability to initiate the EXPAND trial; clinical outcomes, which may materially change as more patient data become available; the likelihood of success of the Phase 2 ALPHA2 trial, which is based on limited data from the Phase 1 ALPHA trials across two different product candidates and various doses of ALLO-501 or ALLO-501A; the ability to optimize manufacturing or manufacture AlloCAR T products, including with the Alloy process, with consistent and reproducible product characteristics; the design and potential benefits of our Dagger technology, including its ability to control rejection of allogeneic CAR T cells; the potential for our product candidates to be approved; the potential benefits of AlloCAR T products and 2023 financial guidance. 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; Servier’s discontinuation of its involvement in the development of all CD19 products pursuant to our Exclusive License and Collaboration Agreement, including disagreements relating to development cost contributions and audit rights related to such contributions, and the timeframe during which we have the right to elect a license to CD19 Products outside of the United States; the limited nature of our Phase 1 data from our clinical trials and the extent to which such data may or may not be validated in any future 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 preclinical studies and clinical trials; the extent to which the Food and Drug Administration disagrees with our regulatory plans, which could cause future delays to our 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-K for the year ended December 31, 2022. 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 our existing or future results.

AlloCAR T™, TurboCAR™, Alloy™ and Dagger™ are trademarks of Allogene Therapeutics, Inc.

Allogene's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. The anti-BCMA and anti-CD70 AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

ALLOGENE THERAPEUTICS, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Collaboration revenue - related party	$ 47	$ 51	$ 243	$ 38,489
Operating expenses:				
Research and development	75,419	53,983	256,387	220,176
General and administrative	21,002	19,961	79,305	74,105
Total operating expenses	96,421	73,944	335,692	294,281
Loss from operations	(96,374)	(73,893)	(335,449)	(255,792)
Other income (expense), net:				
Interest and other income, net	2,757	186	4,566	1,714
Other expenses	(1,230)	(1,161)	(1,749)	(2,927)
Total other income (expense), net	1,527	(975)	2,817	(1,213)
Net loss	(94,847)	(74,868)	(332,632)	(257,005)
Net loss per share, basic and diluted	$ (0.66)	$ (0.54)	$ (2.32)	$ (1.89)
Weighted-average number of shares used in computing net loss per share, basic and diluted	144,149,240	139,173,761	143,147,165	135,820,386

SELECTED BALANCE SHEET DATA

	As of December 31, 2022	As of December 31, 2021
Cash, cash equivalents and investments	$ 576,471	$ 809,481
Total assets	817,079	1,038,634
Total liabilities	151,209	122,228
Total stockholders' equity	665,870	916,406

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