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 3, 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. 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 3, 2023, Allogene Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended March 31, 2023 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 3, 2023.
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 3, 2023

Exhibit 99.1

Allogene Therapeutics Reports First Quarter 2023 Financial Results and Business Update

- Enrollment Ongoing in Industry's First Potentially Pivotal Phase 2 Allogeneic CAR T Trial, ALPHA2, in Relapsed/Refractory Large B Cell Lymphoma
- Initiated Phase 2 EXPAND Trial to Support Licensure of ALLO-647 As a Lymphodepleting Agent for ALLO-501A
- Announced American Society of Clinical Oncology (ASCO) Annual Meeting Presentation of Phase 1 Data from the ALLO-501/501A Trials
- Presented Interim Phase 1 Data on ALLO-316 in Renal Cell Carcinoma at the American Association of Cancer Research (AACR) Annual Meeting
  - Data Provide Proof-of-Concept for an Allogeneic CAR T in Solid Tumors
  - Three of 10 Patients Achieved a Partial Response Following a Single Infusion of ALLO-316; Patients Had Previously Progressed on Standard Therapies that Included an Immune Checkpoint Inhibitor and a VEGF-Targeting Therapy
- Appointed Cell Therapy Pioneer Timothy Moore as Chief Technical Officer
- Ended Q1 2023 with $514 Million in Cash, Cash Equivalents and Investments; Cash Runway Projected Into Q2 2025
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., May 3, 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 ended March 31, 2023.

"Our first quarter progress continues to establish Allogene as the leader in the development of allogeneic CAR T product candidates," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Our success across multiple clinical programs, ability to attract top tier talent, and financial stewardship to weather the challenging external market environment paves the way toward to bringing a new generation of CAR T products to patients."

Pipeline Updates

ALLO-501A: Anti-CD19 AlloCAR T Program
The Company continues to enroll patients in the industry's first potentially pivotal Phase 2 allogeneic CAR T clinical trial with ALLO-501A. The single-arm ALPHA2 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) following lymphodepletion with FCA90 (fludarabine, 30 mg/m2; cyclophosphamide 300 mg/m2; and ALLO-647 30 mg, daily for 3 days). This 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 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 1H 2024.

During the first quarter, the Company initiated the EXPAND trial to support licensure of ALLO-647. The Company is developing ALLO-647, an anti-CD52 monoclonal antibody, to permit the use of standard low-dose FC (fludarabine, 30 mg/m2 and cyclophosphamide 300 mg/m2, daily for 3 days) lymphodepletion regimens across our portfolio. This proprietary regimen is intended to prevent premature rejection, thereby enabling expansion and persistence of AlloCAR T cells and supporting improved clinical performance of product candidates. In the EXPAND trial, approximately 70 patients with R/R LBCL will be randomized to be lymphodepleted with FCA90 (which includes 90 mg of ALLO-647) versus FC alone before receiving a single 120 million cell dose of ALLO-501A. The study is designed to demonstrate the superiority of FCA90 over FC as measured by progression free survival (PFS).

After the close of the quarter, the Company announced that pooled data from the Phase 1 ALPHA/ALPHA2 trials of ALLO-501/501A, in R/R LBCL would be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting June 2 – 6, 2023 in Chicago, Illinois.

ALLO-316: Anti-CD70 AlloCAR T Program
The Company presented interim data from its Phase 1 TRAVERSE trial of ALLO-316, the Company's first AlloCAR T investigational product candidate for solid tumors, during an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting in April.

The ongoing dose escalation study is enrolling patients with advanced or metastatic renal cell carcinoma (RCC) who have progressed on standard therapies that included an immune checkpoint inhibitor and a VEGF-targeting therapy. Emerging data from this trial have demonstrated the potential of an allogeneic CAR T product to treat CD70 expressing RCC. In this trial, ALLO-316 showed early anti-tumor activity with deepening responses over time. The data reported to date is primarily from the DL1 and DL2 cohorts.

Anti-tumor activity was primarily observed in patients with tumors confirmed to express CD70 (N=10). Among 18 patients evaluable for efficacy, the disease control rate (DCR) was 89%. In the 10 patients whose tumors were known to express CD70, the disease control rate was 100%, which included three patients who achieved partial remission (two confirmed, one unconfirmed). The longest response lasted until month eight. There was a trend toward greater tumor shrinkage in patients with higher levels of CD70 expression.

In patients evaluable for safety (N=19), ALLO-316 demonstrated an adverse event profile generally consistent with autologous CAR T therapies. One dose-limiting toxicity of Grade 3 autoimmune hepatitis occurred in the second dose level. Cytokine release syndrome (CRS) was all low-grade with the exception of one Grade 3. Neurotoxicity, which is now defined more broadly, was generally low grade and reversible with most events being fatigue or headache. There were no cases of immune effector cell-associated neurotoxicity syndrome (ICANS). Infections occurred in eight patients of which four were Grade 3+ including one Grade 5 respiratory failure due to Covid-19 infection deemed unrelated to study treatment. Grade 3+ prolonged cytopenia was observed in three patients (16%). There were no cases of graft-versus-host disease (GvHD).

The Dagger™ technology, which is a feature of ALLO-316, is designed to resist rejection of AlloCAR T cells by the host immune cells, thereby supporting expansion and enabling a prolonged window of persistence during which AlloCAR T cells can target and destroy cancer cells. Initial translational data from the TRAVERSE trial demonstrates the suppression of CD70 positive, alloreactive host T cells and marked peak expansion of ALLO-316 despite the relatively low cell doses tested. The Company plans to deploy Dagger technology to potentially enhance the persistence and activity of next generation AlloCAR T products, including those that target other hematological and solid tumors.

The Company has deployed a new investigational in vitro companion diagnostic (IVD) assay designed to prospectively assess CD70 expression levels to enhance patient selection. Dose escalation in the TRAVERSE trial is expected to be completed in 2023.

ALLO-715: Anti-BCMA AlloCAR T Program
During the quarter, data from the Phase 1 UNIVERSAL trial with ALLO-715 for the treatment of r/r multiple myeloma (MM) was published in Nature Medicine. UNIVERSAL 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. The Company is evaluating manufacturing processes improvements across its BCMA candidates to achieve optimal performance.

Corporate Updates
In April, it was announced that Timothy Moore had been appointed as Executive Vice President, Chief Technical Officer. The appointment of Mr. Moore, an industry pioneer responsible for the global development of two of the most commercially successful autologous CAR T manufacturing processes, reinforces the Company’s focus on being the first to bring an AlloCAR T product to market.

First Quarter Financial Results
- Research and development expenses were $80.2 million for the first quarter of 2023, which includes $9.2 million of non-cash stock-based compensation expense.
- General and administrative expenses were $18.9 million for the first quarter of 2023, which includes $9.6 million of non-cash stock-based compensation expense.
- Net loss for the first quarter of 2023 was $98.7 million, or $0.68 per share, including non-cash stock-based compensation expense of $18.8 million.
- The Company had $514 million in cash, cash equivalents, and investments as of March 31, 2023.

2023 Financial Guidance
- The Company now expects a decrease in cash, cash equivalents, and investments of approximately $230 million in 2023. Based on current expectation, the Company expects its cash runway to be sufficient to fund operations into Q2 2025. GAAP Operating Expenses are expected to be approximately $340 million, including estimated non-cash stock-based compensation expense of approximately $80 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 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 @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," “projects,” "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: ALPHA2 being a potentially pivotal trial; expected enrollment and related timelines; the expected timing to complete dose escalation; the potential of an allogeneic CAR T product to treat CD70 express RCC based on emerging data; study design; the timing and ability to progress the ALPHA2 and TRAVERSE trials; clinical outcomes, which may materially change as more patient data become available; ; the ability to achieve optimal clinical performance through manufacturing processes improvements; the design and potential benefits of our Dagger technology, including its ability to resist rejection of AlloCAR T cells by the host immune cells and the expected benefits therefrom, and our plans to deploy Dagger technology; 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 and our disputes with Servier may have adverse consequences; 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 clinical or regulatory plans or the import of our clinical results, which could cause future delays to our 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; 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 in its Annual Report on Form 10-K for the year ended December 31, 2022, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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.

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™ 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 March 31,	
	2023	**2022**
Collaboration revenue - related party	$ 52	$ 61
Operating expenses:		
Research and development	$ 80,238	$ 60,156
General and administrative	18,884	19,897
Total operating expenses	99,122	80,053
Loss from operations	(99,070)	(79,992)
Other income (expense), net:		
Interest and other income, net	2,059	492
Other expenses	(1,693)	(350)
Total other income (expense), net	366	142
Net loss	(98,704)	(79,850)
Net loss per share, basic and diluted	$ (0.68)	$ (0.56)
Weighted-average number of shares used in computing net loss per share, basic and diluted	144,563,829	141,356,306

SELECTED BALANCE SHEET DATA

	As of March 31, 2023	**As of December 31, 2022**
Cash, cash equivalents and investments	$ 514,012	$ 576,471
Total assets	746,871	817,079
Total liabilities	154,609	151,209
Total stockholders' equity	592,262	665,870

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