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 23, 2022

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 23, 2022, Allogene Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the fourth quarter and year ended December 31, 2021 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 23, 2022.

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 23, 2022

Exhibit 99.1

Allogene Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

- AlloCAR T™ Studies Resumed and Currently Enrolling Patients Following Removal of Clinical Hold in January 2022
- Phase 1 Data from the ALPHA Trials in Relapsed/Refractory (RR) Non-Hodgkin Lymphoma Presented at ASH 2021 Demonstrated Potential for an AlloCAR T Product to be a Safe and Durable Alternative to Autologous Cell Therapy in CAR T Naïve Patients
  - Pivotal Phase 2 ALPHA2 Trial of ALLO-501A in R/R Large B Cell Lymphoma on Track to Commence Mid-Year 2022 Pending Ongoing FDA Discussions
- Phase 1 Data Presented at ASH 2021 from the ALLO-715 UNIVERSAL Trial in R/R Multiple Myeloma Demonstrated Potential for an Allogeneic Anti-BCMA CAR T to Achieve Responses Similar to Approved Autologous CAR T Therapy with Added Benefit of Treatment within Five Days of Enrollment and Elimination of Bridging Therapy
- Ended 2021 with $810 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 23, 2022 – 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, 2021.

“The FDA hold placed upon our clinical programs presented us with an unexpected challenge during the fourth quarter. In responding to and resolving this challenge, our team continued to demonstrate the qualities of leadership, collaboration, innovation, and focus that are required to be a pioneer in the field of allogeneic T cell therapy. I am incredibly proud of our employees’ commitment and relentless belief in the potential for our products to improve the lives of patients,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Our mission has been, and continues to be, the first to bring allogeneic CAR T products to the market in blood cancers and solid tumors. We believe we are on track and have what it takes to execute on this vision and look forward to advancing our broad portfolio of product candidates.”

Corporate Highlights

On January 10, 2022, Allogene announced that the U.S. Food and Drug Administration (FDA) had removed the clinical hold on all AlloCAR T clinical trials which was announced on October 7, 2021. After extensive investigation by Allogene, it was determined that the chromosomal abnormality detected in a single patient treated with ALLO-501A was unrelated to TALEN® gene editing or Allogene’s manufacturing process and had no clinical significance. The abnormality was not detected in any manufactured AlloCAR T product or in any other patient treated with the same ALLO-501A lot. The abnormality occurred after the cell product was administered and involved regions of the T cell receptor and immunoglobulin genes known to undergo rearrangement as part of the T cell or B cell maturation process.

Allogene has resumed clinical study activities on ALLO-715 and ALLO-605 for relapsed/refractory (R/R) multiple myeloma (MM), and ALLO-316 for advanced or metastatic clear cell renal cell carcinoma (RCC), and began enrolling patients earlier this month. Enrollment in the Phase 1 ALLO-501 ALPHA trial in R/R non-Hodgkin lymphoma (NHL) has completed accrual. The focus remains on preparing for the pivotal Phase 2 ALPHA2 trial of ALLO-501A in R/R Large B Cell Lymphoma (LBCL). Prior to the start of Phase 2, Allogene plans to resume enrollment in the Phase 1 study in order to offer AlloCAR T to patients in need.

Cell Forge 1 (CF1)

CF1, Allogene’s state-of-the-art manufacturing facility located in Newark, California is now fully operational and producing GMP material with the intent of supplying ALLO-501A for the planned pivotal study.

Pipeline Updates

Anti-CD19 Program

Phase 1 data from the ALPHA trial with ALLO-501 and ALPHA2 trial with ALLO-501A for the treatment of R/R NHL was presented at the 2021 Annual American Society of Hematology (ASH) Annual Meeting. Data from these trials continue to support the promise of Allogene’s platform to provide a safe and durable alternative to approved autologous CAR T therapies in CAR T naïve patients.

Highlights from the ASH 2021 presentation include:

- AlloCAR T was associated with consistent and manageable safety with no dose limiting toxicities (DLTs) or graft-vs-host disease (GvHD) and minimal Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), or Grade 3 cytokine release syndrome (CRS).
- There were no relapses observed in LBCL CAR T naïve patients across trials who had achieved a complete response (CR) at six months with the longest ongoing CRs with ALLO-501 at 18+ months and ALLO-501A at 15+ months.
- One of the most critical advantages of AlloCAR T was further established with more than 97% of enrolled patients able to receive therapy with the median time from enrollment to initiation of treatment of five days in ALPHA and two days in ALPHA2.

Phase 2 Preparation:
The single-arm ALPHA2 trial is on track to begin mid-year 2022 with FDA discussions directed at finalizing clinical trial design and proactively accelerating activities that address Chemistry Manufacturing and Controls (CMC) requirements.

Allogene is developing ALLO-647, its proprietary anti-CD52 monoclonal antibody intended to enable expansion and persistence of AlloCAR T product candidates, including ALLO-501A. Allogene intends to launch a separate registrational trial for ALLO-647 at the time of the pivotal Phase 2 trial for ALLO-501A as part of the concurrent development plan. This trial is intended to demonstrate the safety of ALLO-647 along with its contribution to the overall benefit of the lymphodepletion regimen.

Anti-BCMA AlloCAR T Program
Allogene's anti-BCMA strategy includes the Phase 1 UNIVERSAL trial, which has cohorts evaluating ALLO-715 as a monotherapy, consolidated dosing of ALLO-715 using ALLO-647 to selectively extend the window of lymphodepletion, and ALLO-715 in combination with SpringWorks Therapeutics' investigational gamma secretase inhibitor, nirogacestat. The Phase 1 IGNITE trial is evaluating ALLO-605, Allogene's first TurboCAR™ candidate. TurboCAR technology allows cytokine activation signaling to be engineered selectively into CAR T cells and has shown the ability to improve the potency and persistence of allogeneic cells in preclinical models. Activity in these trials has resumed and Allogene intends to provide a BCMA program clinical update by the end of 2022.

ALLO-715 UNIVERSAL Trial
Data from the UNIVERSAL trial with ALLO-715 as a monotherapy for the treatment of R/R MM was also presented at ASH 2021. The UNIVERSAL trial is the first allogeneic anti-BCMA CAR T to demonstrate safety and substantial efficacy in MM with response rates that are similar to the approved autologous CAR T therapy.

- The data presented at ASH demonstrated that ALLO-715 was well tolerated with no GvHD and a manageable safety profile.
- There was a 71% Overall Response Rate (ORR) at dose level 3 (320 million AlloCAR T+ cells) with lymphodepletion consisting of fludarabine/cyclophosphamide and ALLO-647
    - 46% of patients achieved a Very Good Partial Response or better (VGPR+) including 25% Complete Response or Stringent Complete Response (CR/sCR).
    - 92% of patients with VGPR+ were minimal residual disease (MRD) negative.
    - Median duration of response (DoR) was 8.3 months at the time of data cut-off.
- Importantly, the study highlighted the ability to initiate treatment within five days of enrollment and eliminate the need for bridging therapy.

Solid Tumor AlloCAR T Program

ALLO-316 (anti-CD70) – TRAVERSE Trial

- The Phase 1 trial for Allogene's first AlloCAR T candidate for solid tumors, ALLO-316, is designed to evaluate the safety, tolerability, anti-tumor efficacy, pharmacokinetics, and pharmacodynamics of ALLO-316 in patients with advanced or metastatic clear cell RCC. Clinical trial activities have resumed.

Fourth Quarter and Year-End Financial Results

- Research and development expenses were $54.0 million for the fourth quarter of 2021, which includes $11.1 million of non-cash stock-based compensation expense. For the full year of 2021, research and development expenses were $220.2 million. Research and development expense for the year includes $39.6 million of non-cash stock-based compensation expense.
- General and administrative expenses were $20.0 million for the fourth quarter of 2021, which includes $10.9 million of non-cash stock-based compensation expense. For the full year of 2021, general and administrative expenses were $74.1 million, which includes $41.2 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2021 was $74.9 million, or $0.54 per share, including non-cash stock-based compensation expense of $22.0 million. For the full year of 2021, net loss was $257.0 million, or $1.89 per share, including non-cash stock-based compensation expense of $80.8 million.

- The Company had $810 million in cash, cash equivalents, and investments as of December 31, 2021.

2022 Financial Guidance

- Allogene expects full year GAAP Operating Expenses to be between $360 million and $390 million including estimated non-cash stock-based compensation expense of $90 million to $100 million and excluding 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. To access the live conference call by telephone, please dial 1 (866) 940-5062 (U.S.) or 1 (409) 216-0618 (International). The conference ID number for the live call is 4973864. The 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 ALPHA, ALPHA2, UNIVERSAL, IGNITE and TRAVERSE trials, including advancing to the Phase 2 portion of the ALPHA2 trial; the timing and ability to initiate a registration trial for ALLO-647; clinical outcomes, which may materially change as more patient data become available; the ability to manufacture AlloCAR T™ products, including obtaining FDA agreement to use ALLO-501A manufactured at the Company’s manufacturing facility for use in the ALPHA2 trial; the potential benefits of AlloCAR T products; and 2022 financial guidance. Various factors may cause differences between Allogene’s expectations and actual results as discussed in greater detail in Allogene’s filings with the SEC, including without limitation in its Form 10-K for the year ended December 31, 2021. 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.

Statements comparing autologous CAR T data with AlloCAR T data should be viewed with caution, as they involve interpreting results from separate trials involving separate product candidates. 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 the autologous CAR T products may have no interpretative value on our existing or future results.

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. while Servier retains exclusive rights for all other countries. 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,	
	2021	2020	2021	2020
Collaboration revenue - related party	$ 51	$ —	$ 38,489	$ —
Operating expenses:				
Research and development	53,983	52,228	220,176	192,987
General and administrative	19,961	17,134	74,105	65,256
Total operating expenses	73,944	69,362	294,281	258,243
Loss from operations	(73,893)	(69,362)	(255,792)	(258,243)
Other income (expense), net:				
Interest and other income, net	186	1,558	1,714	9,164
Other expenses	(1,161)	(766)	(2,927)	(1,142)
Total other income (expense), net	(975)	792	(1,213)	8,022
Net loss	(74,868)	(68,570)	(257,005)	(250,221)
Net loss per share, basic and diluted	$ (0.54)	$ (0.53)	$ (1.89)	$ (2.08)
Weighted-average number of shares used in computing net loss per share, basic and diluted	139,173,761	129,835,293	135,820,386	120,370,177

SELECTED BALANCE SHEET DATA

	As of December 31, 2021	As of December 31, 2020
Cash, cash equivalents and investments	$ 809,481	$ 1,032,118
Total assets	1,038,634	1,227,829
Total liabilities	122,228	148,212
Total stockholders' equity	916,406	1,079,617

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