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): November 2, 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. 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 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 November 2, 2022, Allogene Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended September 30, 2022 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 November 2, 2022.
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: November 2, 2022

Exhibit 99.1

Allogene Therapeutics Reports Third Quarter 2022 Financial Results and Announces Investor R&D Showcase

- Initiated the Industry's First Allogeneic CAR T Phase 2 Trial
  - ALPHA2 Trial, Evaluating ALLO-501A in Relapsed/Refractory Large B Cell Lymphoma Patients, is Designed to Leverage the Ease and Convenience of a Single Dose of ALLO-501A
  - Readiness Activities Underway for Initiation of the EXPAND Trial, Intended to Demonstrate the Contribution of ALLO-647 to the Standard Lymphodepletion Regimen
- Company to Host Research & Development Showcase on November 29, 2022
  - Event will Feature Updated Clinical Data from the CD19 and BCMA Programs
- Ended Third Quarter with $637 Million in Cash, Cash Equivalents and Investments
- Quarterly Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., November 2, 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 ended September 30, 2022.

The Company also announced an in-person and virtual Research & Development Showcase on Tuesday, November 29, 2022 in New York City. This event will discuss the Company's CD19 program and data supporting the launch of ALPHA2, the first allogeneic CAR T Phase 2 clinical trial as well as updated data from the UNIVERSAL trial with single dose ALLO-715 and next steps for the program.

"We are incredibly proud of our teams and their strong execution which have enabled an industry first – the initiation of our potentially pivotal Phase 2 ALPHA2 trial," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Our leading AlloCAR T programs ALLO-501A and ALLO-715 directed at CD19 and BCMA, respectively, have made substantial progress in 2022. We look forward to providing a comprehensive update on this progress at our upcoming R&D Showcase at the end of the month."

Pipeline Updates

CD19 Program

Allogene has initiated the industry's first potentially pivotal allogeneic CAR T Phase 2 clinical trial of ALLO-501A (ALPHA2 trial) in patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL). The single-arm trial will utilize a single dose of ALLO-501A at 120 million CAR+ cells with a lymphodepletion regimen (FCA90) comprised of fludarabine (30 mg/m2/day x 3 days) and cyclophosphamide (300 mg/m2/day x 3 days) plus ALLO-647 (90 mg). 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).

The Company is in the process of initiating the EXPAND trial, a separate registrational trial that is intended to demonstrate the contribution of ALLO-647 to the standard fludarabine and cyclophosphamide lymphodepletion regimen. Patients will be randomized to receive the same single 120 million cell dose of ALLO-501A as in the ALPHA2 trial and either lymphodepletion with fludarabine and cyclophosphamide alone (control arm) or the same lymphodepletion regimen of the ALPHA2 trial (active arm). The trial is expected to enroll approximately 70 patients with r/r LBCL. The primary endpoint of this trial is progression free survival, and the key secondary endpoints are ORR, DoR, and the safety of ALLO-647.

Allogene's Alloy™ manufacturing process will be deployed in the ALPHA2 and EXPAND trials. Updated clinical data from the CD19 program will be provided at the Company's R&D Showcase on November 29, 2022.

BCMA Program

The Phase 1 UNIVERSAL trial of ALLO-715 continues enrolling patients with r/r multiple myeloma (MM). The Company will provide a clinical update from UNIVERSAL focused on a single dose ALLO-715 and discuss next steps for the program at the R&D Showcase.

Solid Tumor Program

ALLO-316, the Company's first AlloCAR T candidate for solid tumors, targets CD70 and is being studied in patients with advanced or metastatic clear cell renal cell carcinoma (RCC) in the Phase 1 TRAVERSE trial.

Corporate Highlights

CAR T Together™

The Company launched CAR T Together, a first-of-its-kind effort comprised of leading clinical trial investigators who represent the field of clinicians committed to supporting the development of off-the-shelf CAR T products to make CAR T therapy scalable and more accessible to patients with certain cancers. CAR T Together was created in response to several real-world access challenges that have emerged since the commercial introduction of autologous CAR T five years ago, highlighted by a new survey[1] of U.S. based academic centers specializing in the administration of CAR T. This survey found that 82% of respondents agreed that CAR T therapies have changed how they manage aggressive cancers, but extensive wait times and manufacturing limitations keep many eligible patients from receiving treatment. Additional survey results revealed:

- Only half of late-stage cancer patients who are eligible for currently FDA approved autologous CAR T therapies receive treatment.
- Of those patients eligible for treatment, only 12% are able to receive treatment within one month, with approximately 40% waiting three to six months or longer to receive treatment as their disease worsens.
- For eligible patients, disease progression, manufacturing capacity and comorbidities were the top barriers.
- Increased patient demand, manufacturing capacity and time to treatment are cited by respondents as the three biggest challenges facing CAR T adoption in the future.

CAR T Together aims to support innovation and bring awareness to clinical trials that may ultimately lead to the availability of an allogeneic CAR T product for patients. Learn more at www.CARTTogether.com.

Allogene-Overland Biopharm

Allogene Overland Biopharm (Allogene Overland), the Company's joint venture with Overland Pharmaceuticals, announced the completed buildout of a new, commercializable manufacturing facility in Shanghai, China. Allogene Overland is focused on the development, manufacturing and commercialization of AlloCAR T therapies for patients in greater China, Taiwan, South Korea and Singapore. The joint venture has exclusive license to develop, manufacture and commercialize specific Allogene candidates targeting BCMA, CD70, FLT3, and DLL3 in the licensed territories.

Third Quarter Financial Results

- Research and development expenses were $63.6 million for the third quarter of 2022, which includes $11.0 million of non-cash stock-based compensation expense.
- General and administrative expenses were $18.9 million for the third quarter of 2022, which includes $10.1 million of non-cash stock-based compensation expense.
- Net loss for the third quarter of 2022 was $83.1 million, or $0.58 per share, including non-cash stock-based compensation expense of $21.1 million.
- The Company had $637 million in cash, cash equivalents, and investments as of September 30, 2022.

2022 Financial Guidance

The Company expects full year GAAP Operating Expenses to be slightly below the low end of its prior guidance of $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. Cash burn for 2022 is expected to be less than $250 million.

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

[1] The survey was sponsored by Allogene Therapeutics and conducted by an independent third-party research organization. The survey did not assess the treatment status of individual patients.

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, EXPAND, UNIVERSAL, and TRAVERSE trials, including initiating the EXPAND trial; clinical outcomes, which may materially change as more patient data become available; the ability to manufacture AlloCAR T™ products, including with the Alloy process; the ability to enroll patients in clinical trials; the ability of Allogene Overland to manufacture AlloCAR T cells and initiate any clinical trials in its territories; the results from the *CAR T Together* survey, which may not be representative of all CAR T treatment providers and may change as the treatment landscape evolves; the potential benefits of AlloCAR T products; and 2022 financial guidance. Various factors may cause material 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-Q for the quarter ended September 30, 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.

Allogene’s AlloCAR T™ programs utilize the Cellectis TALEN® 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 September 30,	
	2022	**2021**
Collaboration revenue - related party	$ 49	$ 49
Operating expenses:		
Research and development	$ 63,641	$ 58,720
General and administrative	18,897	18,999
Total operating expenses	82,538	77,719
Loss from operations	(82,489)	(77,670)
Other income (expense), net:		
Interest and other income, net	1,002	393
Other expenses	(1,661)	(909)
Total other income (expense), net	(659)	(516)
Net loss	(83,148)	(78,186)
Net loss per share, basic and diluted	$ (0.58)	$ (0.57)
Weighted-average number of shares used in computing net loss per share, basic and diluted	143,661,721	137,025,698

SELECTED BALANCE SHEET DATA

	As of September 30, 2022	**As of December 31, 2021**
Cash, cash equivalents and investments	$ 637,337	$ 809,481
Total assets	887,572	1,038,634
Total liabilities	147,611	122,228
Total stockholders' equity	739,961	916,406

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