

**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 7, 2019

Allogene Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38693
(Commission
File Number)

82-3562771
(I.R.S. Employer
Identification No.)

210 East Grand Avenue
South San Francisco, California
(Address of principal executive offices)

94080
(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))

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.

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

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Allogene Therapeutics, Inc. (the “Company”) provided a corporate update and announced its financial results for the first quarter ended March 31, 2019 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)

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press Release of the Company, dated May 7, 2019.</u>

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 7, 2019

Allogene Therapeutics Reports First Quarter 2019 Financial Results

- Initiated ALLO-501 Phase 1 ALPHA Trial in Patients with Relapsed/Refractory Non-Hodgkin Lymphoma (NHL)
- Investigational New Drug (IND) Application Submitted to the U.S. Food & Drug Administration (FDA) for ALLO-715 Targeting BCMA for the Treatment of Patients with Relapsed/Refractory Multiple Myeloma
- Ended First Quarter 2019 with \$681 Million in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for 5:30 AM PT/8:30 AM ET

South San Francisco, Calif., May 7, 2019 – Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, today provided a corporate update and reported financial results for the quarter ended March 31, 2019.

“We are very pleased with our ability to accelerate the research and development activities for both ALLO-501 and ALLO-715,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Our focus from day one has been on the acceleration of AlloCAR T therapy to enable an “off-the-shelf” CAR T therapy for patients. In May 2018, we started Allogene with approximately 40 employees. Today, we have over 150 employees, all dedicated to making AlloCAR T therapy a reality.”

Recent Highlights

ALLO-501 (anti-CD19 AlloCAR T)

- The ALLO-501 Phase 1 ALPHA trial for patients with relapsed/refractory non-Hodgkin lymphoma (NHL) has been initiated. The trial is designed to assess the safety and tolerability at increasing dose levels of ALLO-501 in the most common NHL subtypes of relapsed/refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL), and follicular lymphoma (FL). Multiple sites with expertise in CAR T are fully activated and the Company continues to expect to report initial data from the trial in the first half of 2020.
- The Company is rapidly progressing the planned second generation of ALLO-501 through preclinical development. The second generation ALLO-501 is devoid of the rituximab off-switch and is expected to be introduced prior to the start of the Phase 2 portion of the ALPHA study.

ALLO-715 (anti-BCMA AlloCAR T)

- An Investigational New Drug (IND) application has been submitted to the U.S. Food & Drug Administration (FDA) for ALLO-715, a wholly-owned CAR T product candidate targeting B cell maturation antigen (BCMA) for relapsed/refractory multiple myeloma. The Company remains on track to initiate a Phase 1 trial in 2019.

- In April, the Company published in the journal *Molecular Therapy* preclinical study results validating the potential for an AlloCAR T to treat multiple myeloma. These results demonstrated the ability for ALLO-715 to sustain potent anti-tumor responses in pre-clinical models.

Additional Pipeline Updates

- **UCART19 (Servier-Sponsored Program in Collaboration with Allogene).** Servier is in the process of advancing its supply and re-initiating recruitment for the CALM and PALL trials in relapsed/refractory acute lymphoblastic leukemia. UCART19 is expected to be advanced to potential registrational trials in 2020.
- **CD70 -** At the 2019 American Association for Cancer Research (AACR) Annual Meeting, the Company presented pre-clinical data on its AlloCAR T program targeting CD70, a cancer target that is expressed on both hematologic and solid tumor cells. The data demonstrated the therapeutic potential of an AlloCAR T therapy directed at CD70 in renal cell carcinoma (RCC). The Company plans to select an anti-CD70 AlloCAR T candidate for IND-enabling studies.

Corporate

In May, the Company announced the expansion of its Scientific Advisory Board (SAB) with the appointment of Robert Abraham, Ph.D., Malcolm K. Brenner, M.D., Ph.D., Stephen J. Forman, M.D., and Wendell Lim, Ph.D.

First Quarter Financial Results

- Research and development expenses were \$23.4 million for the first quarter of 2019, which includes \$2.7 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$13.1 million for the first quarter of 2019, which includes \$5.1 million of non-cash stock-based compensation expense.
- Net loss for the first quarter of 2019 was \$31.6 million, or \$0.32 per share, including non-cash stock-based compensation expense of \$7.9 million.
- As of March 31, 2019, Allogene had \$680.7 million in cash, cash equivalents, and investments.
- The Company continues to expect full-year 2019 net losses to be between \$200 million and \$210 million dollars, including estimated non-cash stock-based compensation expense of \$45 million to \$50 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 5:30 AM Pacific Time/8:30 AM 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 6179933. 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™) therapies for cancer. Led by a world-class management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T

cell therapy 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 ALLO-501 ALPHA trial, the timing and ability to report initial clinical results from the ALPHA trial, the ability to introduce the second generation of ALLO-501 prior to the start of the Phase 2 portion of the ALPHA trial, the timing and ability to initiate and progress a clinical trial of ALLO-715, Servier’s ability to re-initiate enrollment in the CALM and PALL trials, the timing and ability to progress the CALM and PALL trials to potential registrational trials, the ability to manufacture AlloCAR T™ therapies, the ability to initiate and progress additional clinical trials of AlloCAR T™ therapies, the potential benefits of AlloCAR T™ therapy and the 2019 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 Securities and Exchange Commission (SEC), including without limitation in its Form 10-K for the year ended December 31, 2018. 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 THERAPEUTICS, INC.**SELECTED FINANCIAL DATA**

(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 23,403	\$ —
General and administrative	13,058	2,597
Total operating expenses	36,461	2,597
Loss from operations	(36,461)	(2,597)
Interest and other income, net	4,825	—
Total other income (expense), net	(31,636)	(2,597)
Loss before income taxes	(31,636)	(2,597)
Benefit from income taxes	50	—
Net loss	(31,586)	(2,597)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.10)
Weighted-average number of shares used in computing net loss per share, basic and diluted	97,315,890	26,249,993

SELECTED BALANCE SHEET DATA

	As of March 31,
	2019
Cash, cash equivalents and investments	\$ 680,728
Total assets	749,369
Total liabilities	68,141
Total stockholders' equity	681,228

Allogene Media/Investor Contact:

Christine Cassiano

Chief Communications Officer

(714) 552-0326

Christine.Cassiano@allogene.com