# **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 5, 2019

$\mathcal{C}$	ne Therapeutics,	
(Exact na	me of registrant as specified in its cha	rter)
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 (Address of principal executive offices)		94080 (Zip Code)
	whone number, including area code: (6: nme or former address, if changed since last rep	
Check the appropriate box below if the Form 8-K filing is interprovisions (see General Instruction A.2. below):	ended to simultaneously satisfy the filing	obligation of the registrant under any of the following
☐ Written communications pursuant to Rule 425 ur	nder the Securities Act (17 CFR 230.425	)
☐ Soliciting material pursuant to Rule 14a-12 unde	r the Exchange Act (17 CFR 240.14a-12	2)
☐ 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 of this chapter) or Rule 12b–2 of the Securities Exchange Act		d in Rule 405 of the Securities Act of 1933 (§ 230.405
Emerging growth company x		
If an emerging growth company, indicate by check mark if the revised financial accounting standards provided pursuant to S		ended transition period for complying with any new or
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 November 5, 2019, Allogene Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended September 30, 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)		
Exhibit		
Number	Description	
99.1	Press Release of the Company, dated November 5, 2019.	

# **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 5, 2019



#### Allogene Therapeutics Reports Third Quarter 2019 Financial Results

- Initiated ALLO-715 Phase 1 UNIVERSAL Trial in Relapsed/Refractory Multiple Myeloma (MM)
- Patient Accrual Ongoing for ALLO-501 Phase 1 ALPHA Trial in Relapsed/Refractory Non-Hodgkin Lymphoma (NHL) with Data Expected in First Half of 2020
- Entered into Exclusive Collaboration with Notch Therapeutics to Develop Next Generation iPSC-Based Cell Therapies
- Ended Third Quarter 2019 with \$601.9 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., November 5, 2019 - Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T<sup>TM</sup>) therapies for cancer, today provided a corporate update and reported financial results for the quarter ended September 30, 2019.

"I am very pleased with the progress we have made in a short period of time. While we leveraged the research from Pfizer to launch Allogene, we have built the company from the ground up. In parallel, we have initiated the build-out of in-house manufacturing capabilities, successfully progressed AlloCAR T programs into Phase 1 clinical development while creating next generation therapies and entering into agreements that will keep us at the forefront of cell therapy," said David Chang, M.D., Ph.D., President, CEO and Co-Founder of Allogene Therapeutics. "With the initiation of our ALLO-715 Phase I UNIVERSAL trial in multiple myeloma, we have achieved all of the clinical goals that we set out for ourselves at the beginning of 2019. I am very proud of our team's accomplishments and firmly believe that the time and investment Allogene is making in research, next generation technologies, manufacturing and personnel will provide us with the key building blocks needed to support our goal of being the first to bring an AlloCAR T therapy to patients."

#### **Pipeline Highlights**

#### ALLO-501 (anti-CD19 AlloCAR T)

 ALLO-501 Phase 1 ALPHA trial in patients with relapsed/refractory non-Hodgkin lymphoma (NHL) continues to accrue as planned with data expected in the first half of 2020.

#### ALLO-715 (anti-BCMA AlloCAR T)

- The Company initiated the ALLO-715 Phase 1 UNIVERSAL trial in patients with relapsed/refractory multiple myeloma (MM).
- The Phase 1 ALLO-715 UNIVERSAL trial is designed to assess the safety and tolerability at increasing dose levels of ALLO-715 to identify an optimal dose of ALLO-715 for the potential Phase 2 study. This trial utilizes ALLO-647, the Company's proprietary anti-CD52 monoclonal antibody, as a part of the lymphodepletion regimen. The UNIVERSAL trial also includes the potential to evaluate alternative lymphodepletion regimens that do not include fludarabine and cyclophosphamide.
- ALLO-715 utilizes TALEN® gene-editing technology pioneered and owned by Cellectis. Allogene has an exclusive license to the Cellectis
  technology for allogeneic products directed at the BCMA target. Allogene holds global development and commercial rights for this investigational
  candidate.

#### **Additional Pipeline Updates**

• UCART19 (Servier-Sponsored Program in Collaboration with Allogene) - Servier continues to expect that

UCART19, an anti-CD19 AlloCAR T being developed for pediatric and adult relapsed/refractory acute lymphoblastic leukemia (ALL), will advance into potential Phase 2 registrational trials in 2020.

#### **Corporate Highlights**

- Earlier today, the Company announced a worldwide collaboration with Notch Therapeutics to develop induced Pluripotent Stem Cell (iPSC)derived allogeneic therapies for hematologic cancer indications.
- The Company will receive exclusive rights and targets for initial applications in non-Hodgkin lymphoma, leukemia and multiple myeloma and has made an equity investment in Notch. Notch will receive an upfront payment, research funding, development and commercial milestones, and royalties on net sales.
- Notch was established in 2018 by Juan Carlos Zúñiga-Pflücker, Ph.D. and Peter Zandstra, Ph.D., recognized pioneers in iPSC and T cell differentiation technology.

#### **Third Quarter Financial Results**

- As of September 30, 2019, Allogene had \$601.9 million in cash, cash equivalents, and investments.
- Research and development expenses were \$40.0 million for the third quarter of 2019, which includes \$5.5 million of non-cash stock-based compensation expense, compared to \$10.9 million for the third quarter of 2018. Research and development expenses also included a \$5.0 million milestone to Cellectis that is associated with the initiation of the ALLO-715 UNIVERSAL trial.
- General and administrative expenses were \$15.0 million for the third quarter of 2019, which includes \$7.3 million of non-cash stock-based compensation expense, compared to \$11.3 million for the third quarter of 2018.
- Net loss for the third quarter of 2019 was \$50.7 million, or \$0.50 per share, including non-cash stock-based compensation expense of \$12.8 million, compared to a net loss of \$43.5 million, or \$10.71 per share for the third quarter of 2018.
- Including expenses associated with the Notch transaction, the Company reiterates full-year 2019 Net Loss guidance of between \$200 million and \$210 million dollars, which includes an estimated non-cash stock-based compensation expense of \$45 to \$50 million dollars, and excludes any impact from future 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 2747063. The webcast will be made available on the Company's website at <a href="https://www.allogene.com">www.allogene.com</a> 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<sup>TM</sup>) 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 <a href="www.allogene.com">www.allogene.com</a>, 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 and ALLO-715 UNIVERSAL trial, the timing and Servier's ability to progress the CALM and PALL trials to potential registrational trials, the ability to

manufacture AlloCAR T<sup>TM</sup> therapies, the ability to initiate and progress additional clinical trials of AlloCAR T<sup>TM</sup> therapies, the potential benefits of AlloCAR T<sup>TM</sup> 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-Q for the quarter ended June 30, 2019. 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 September 30,		Nine Months Ended September 30,				
		2019	2018		2019		2018
Operating expenses:							
Research and development	\$	39,995	\$ 10,870	\$	95,172	\$	133,356
General and administrative		15,016	11,317		42,261		26,440
Total operating expenses		55,011	22,187		137,433		159,796
Loss from operations		(55,011)	(22,187)		(137,433)		(159,796)
Other income (expense), net:							
Change in fair value of convertible note payable		_	(19,415)		_		(19,415)
Interest expense		_	(3,358)		_		(3,358)
Interest and other income, net		4,309	1,463		13,693		1,573
Loss before income taxes		(50,702)	(43,497)		(123,740)		(180,996)
Benefit from income taxes		(33)	_		176		_
Net loss		(50,735)	(43,497)		(123,564)		(180,996)
Net loss per share, basic and diluted	\$	(0.50)	\$ (10.71)	\$	(1.24)	\$	(16.38)
Weighted-average number of shares used in computing net loss per share, basic and diluted		102,186,644	4,060,419		99,801,001		11,048,451

# SELECTED BALANCE SHEET DATA

	As of September 30, 2019			As of December 31, 2018			
Cash, cash equivalents and investments	\$	601,946	\$	721,350			
Total assets		695,544		773,855			
Total liabilities		75,828		70,691			
Total stockholders' equity		619,716		703,164			

# Allogene Media/Investor Contact:

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