FATE THERAPEUTICS INC
Form 8-K
December 12, 2017

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): December 11, 2017

Fate Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-36076	65-1311552
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

3535 General Atomics Court, Suite 200

San Diego, CA 92121
(Address of principal executive offices, including zip code)

(858) 875-1800

(Registrant's telephone number, including area code)

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:

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 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 8.01 Other Events

On December 11, 2017, Fate Therapeutics, Inc. (the "Company") announced Day 100 clinical data from the Phase 1 stage of its PROTECT clinical trial of ProTmune™, the Company's next-generation hematopoietic cell graft for patients

with hematologic malignancies (“PROTECT”). These data were also presented by Richard Maziarz, M.D., Principal Investigator, Oregon Health Sciences University, during a poster session at the 59th American Society of Hematology Annual Meeting and Exposition on December 11, 2017.

ProTmune™ Clinical Progress

The Phase 1 stage of PROTECT included seven adult subjects with hematologic malignancies undergoing matched unrelated donor hematopoietic cell transplantation (HCT) following myeloablative conditioning. Of the seven subjects with hematologic malignancies, there were three with acute lymphoblastic leukemia (ALL), three with acute myeloid leukemia (AML) and one with myelodysplastic syndrome (MDS). During the first 100 days following HCT, all seven subjects receiving ProTmune remained alive and relapse-free. Three of the seven subjects experienced acute graft-versus-host disease (GvHD) during the first 100 days following HCT, all of whom responded to standard-of-care steroid treatment. The median time to resolution of the maximum GvHD grade was 7 days [range: 5-8 days]. There were no events of graft failure, and there were no ProTmune-related serious adverse events reported by investigators.

PROTECT Day 100 Clinical Data							
Subject	1	2	3	4	5	6	7
Hematologic Malignancy	MDS	AML	AML	ALL	ALL	ALL	AML

CD34+ cell dose (x10^6/kg)	10.3	4.6	10.9	4.8	3.2	3.0	9.4
CD3+ cell dose (x10^8/kg)	3.1	1.8	2.6	2.8	2.0	1.2	2.8
ProTmune-related SAEs	None	None	None	None	None	None	None
Day of Neutrophil Engraftment [1]	Day 14	Day 18	Day 22	Day 15	Day 16	Day 18	Day 19
Acute GvHD / Grade (CIBMTR)	None	None	Grade 2	None	Grade 2	Grade 3	None
Treatment Responsive	---	---	Yes	---	Yes	Yes	---
Time to Resolution of Maximum Grade	---	---	7 days	---	8 days	5 days	---
Cancer Relapse-free	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Survival	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[1] As measured from the day following HCT

All subjects receiving ProTmune in the PROTECT Phase 1 stage are being followed for a period of two years following HCT. As of a November 29, 2017 data cut-off, all subjects remained relapse-free, and there were no events of graft failure and no serious adverse events related to ProTmune reported by investigators. Non-relapse mortality was reported in two subjects (Subject 1 on Day 228; Subject 3 on Day 151). Five of seven subjects remained on study with median time on study of 154 days [Day 106 – 254].

PROTECT Phase 2 Design

The Phase 2 stage of PROTECT is a randomized, controlled and double-blinded clinical trial assessing the safety and efficacy of ProTmune in up to 60 adult subjects with hematologic malignancies undergoing matched unrelated donor HCT following myeloablative conditioning. Subjects are being randomized, in a 1:1 ratio, to receive either ProTmune or a conventional matched unrelated donor mobilized peripheral blood cell graft. The primary efficacy endpoint of PROTECT is cumulative incidence of Grades 2-4 acute GvHD by Day 100 following HCT. Additional endpoints, such as rates of cancer relapse, chronic GvHD, non-relapse mortality and overall survival, are also being assessed. Fourteen U.S. centers are currently open for enrollment in the Phase 2 stage of PROTECT.

About ProTmune™

ProTmune™ is an investigational next-generation hematopoietic cell graft for the prevention of acute graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic cell transplantation. ProTmune is manufactured by pharmacologically modulating a donor-sourced, mobilized peripheral blood graft ex vivo with two small molecules (FT1050 and FT4145) to decrease the morbidity and mortality of acute GvHD while maintaining the anti-leukemia activity of the graft. ProTmune has been granted Orphan Drug and Fast Track Designations by the U.S. Food and Drug Administration, and Orphan Medicinal Product Designation by the European Commission.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements including statements regarding the therapeutic potential of ProTmune™, the Company’s clinical development plans for ProTmune™, and anticipated data and results from the Company’s ongoing PROTECT clinical trials. These and any other forward-looking statements are based on the Company’s current expectations and are subject to a number of risks and uncertainties that could cause actual results

to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the results of ProTmune™ observed in preclinical studies and clinical trials to date may not be replicated in Phase 1 or 2 of PROTECT or in subsequent clinical trials of ProTmune™; the results observed in the Phase 1 stage of PROTECT to date represent only interim results for a limited number of patients and final results may differ materially, ProTmune™ may be observed to cause unanticipated adverse effects or may fail to meet one or more clinical endpoints, and the Company may cease or delay clinical development activities for a variety of reasons (including additional requirements that may be imposed by regulatory authorities, changes in regulatory approval pathways, difficulties or delays in patient enrollment, and any adverse events or other negative results that may be observed during clinical development). For a discussion of other risks and uncertainties, any of which could cause actual results to differ materially from those contained in or implied by the forward-looking statements in this Current Report on Form 8-K, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's Form 10-Q for the quarter ended September 30, 2017 and subsequent periodic reports filed by the Company under the Securities Exchange Act of 1934, as amended. The Company is providing the information in this Current Report on Form 8-K as of the date hereof and does not undertake any obligation to update any forward-looking statements contained in this report unless required by applicable law.

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.

Date: December 12, 2017 Fate Therapeutics, Inc.

By: /s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer