FATE THERAPEUTICS INC
Form 8-K
May 06, 2015

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 6, 2015**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On May 6, 2015, Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of the Company will present a clinical update on the Company s ongoing Phase 2 clinical trial of its PROHEMA® product candidate (the PUMA study) during a Company presentation at the Deutsche Bank 40th Annual Health Care Conference in Boston, MA.

The clinical update includes data from 18 subjects in the PROHEMA cohort and 12 subjects in the concurrent control cohort. The majority of subjects in both cohorts had acute leukemia (acute myeloid leukemia, acute lymphocytic leukemia or biphenotypic leukemia). Fifteen of the 18 PROHEMA subjects and 10 of the 12 concurrent control subjects received myeloablative conditioning (MAC) prior to transplant; the remaining subjects in each cohort received reduced-intensity conditioning (RIC). Eleven of the 18 PROHEMA subjects, and 11 of the 12 concurrent control subjects, tested sero-positive for cytomegalovirus (CMV) at baseline. Key baseline characteristics of the cohorts are summarized in Table 1.

Table 1: Baseline Characteristics

	PROHEMA	**Concurrent Control**
Number of subjects	18	12
Median Age (range), years	36.4 (18-64)	34.9 (20-54)
Median Weight (range), kg	68.5 (48-101)	78.4 (41-109)
Sex (M/F)	10 / 8	7 / 5
Diagnosis		
Acute leukemia	15	9
Non-Hodgkin / Hodgkin lymphoma	2	2
Other hematologic malignancy	1	1
Other		
Conditioning regimen (MAC / RIC)	15 / 3	10 / 2
CMV sero-status at baseline (positive / negative)	11 / 18	11 / 12

Neutrophil Engraftment

Based on an analysis of the currently available data, subjects who were administered PROHEMA had both an increased incidence of early neutrophil engraftment and a reduction in median time of neutrophil engraftment, as compared to pre-specified historical control medians (which have been established as 26 days for subjects receiving MAC and 21 days for subjects receiving RIC).

Specifically, 14 of 18 subjects who were administered PROHEMA achieved neutrophil engraftment, and nine of those 14 subjects (64%) engrafted prior to the applicable historical control median. The reduction in median time to neutrophil engraftment in the PROHEMA cohort was six days as compared to the historical control values.

By comparison, 11 of 12 concurrent control subjects achieved neutrophil engraftment, and six of those 11 subjects (55%) engrafted prior to the applicable historical control median. The reduction in median time to neutrophil engraftment in the concurrent control cohort was one day as compared to the historical control values.

Based on an analysis of the currently available data, subjects who were administered PROHEMA had both an increased incidence of early neutrophil engraftment (64%) and a reduction in median time of neutrophil engraftment (five days) as compared to the concurrent control cohort. Data from the concurrent control cohort is being used to provide context for validating the pre-specified historical control values for neutrophil engraftment and for interpreting other clinical outcomes.

CMV Reactivation

Under the protocol for the PUMA study, subjects are tested weekly for CMV reactivation during the first 100 days post-transplant using quantitative PCR assays employed by the participating transplant centers. Based on an analysis of the currently available data, CMV sero-positive subjects administered PROHEMA had both a reduced incidence of CMV reactivation and a reduction in the proportion of tests that were positive for CMV during the first 100 days post-transplant, as compared to CMV sero-positive subjects in the concurrent control group.

Specifically, CMV reactivation was observed in seven of the 11 PROHEMA subjects (64%) who tested sero-positive for CMV at baseline, as compared to 11 of 11 concurrent control subjects (100%) who tested sero-positive for CMV at baseline. Additionally, among CMV sero-positive subjects who had reached at least 100 days post-transplant, 14% of tests (14 of 101) were positive for CMV reactivation in subjects administered PROHEMA (n=8), as compared to 23% of tests (29 of 125) that were positive for CMV reactivation in the concurrent control cohort (n=9).

Infection-Related Adverse Events

Based on an analysis of the currently available data, subjects administered PROHEMA had both a reduced incidence of infection-related adverse events and a reduction in the number of infection-related adverse events, as compared to the concurrent control cohort.

Specifically, 10 of 18 subjects administered PROHEMA (56%) experienced at least one infection-related adverse event, and these 10 subjects experienced a total of 13 infection-related adverse events (1.3 per subject). By comparison, eight of 12 concurrent control subjects (67%) experienced at least one infection-related adverse event, and these eight subjects experienced a total of 19 infection-related adverse events (2.4 per subject).

Among all 18 subjects administered PROHEMA, no adverse events of CMV infection (0%) and six adverse events of bacterial infection (33%) have been reported. Among all 12 concurrent control subjects, four adverse events of CMV infection (33%) and seven adverse events of bacterial infection (58%) have been reported.

Safety Assessment

An independent Data Monitoring Committee (iDMC) is providing safety oversight during the conduct of the PUMA study. In December 2014, the PUMA study s independent Data Monitoring Committee conducted a pre-planned interim safety review on a total of 12 subjects that received PROHEMA. At the time of the review, two early deaths prior to engraftment, which were both attributed to the toxicity of the conditioning regimen received by the subjects, were reported in the PROHEMA arm; and one subject administered PROHEMA failed to achieve

neutrophil engraftment. Based on its consideration of the data available as well as historical outcomes reported from multi-center clinical experiences, the iDMC determined that PROHEMA had met pre-established safety criteria and supported continuation of the PUMA study. Since the time of the iDMC s review in December 2014, one subject administered PROHEMA failed to achieve neutrophil engraftment. The Company believes that the nature and frequency of these adverse events are consistent with the complications typically seen in adult patients undergoing umbilical cord blood transplantation for the treatment of hematologic malignancies.

About The PUMA Study

The PUMA (PROHEMA® in UMbilical cord blood transplant in Adults) study is an ongoing, randomized, open-label Phase 2 clinical trial of PROHEMA in adult subjects undergoing double umbilical cord blood transplantation for the treatment of hematologic malignancies. The PUMA study is designed to enroll approximately 60 subjects, randomized at a ratio of 2:1, with approximately 40 subjects intended to receive PROHEMA plus an unmanipulated cord blood unit (PROHEMA cohort), and approximately 20 subjects intended to receive two unmanipulated cord blood units (concurrent control cohort). The primary endpoint of the PUMA study is based on a categorical analysis of neutrophil engraftment, and the clinical trial is powered to show with statistical significance that 70% of subjects with neutrophil engraftment in the PROHEMA treatment arm engraft prior to the pre-specified historical control day of neutrophil engraftment. Multiple exploratory clinical endpoints are being investigated in the PUMA study to inform and support potential registrational strategies including key measures of hematopoietic reconstitution and the immunotherapeutic potential of PROHEMA, such as time to and incidence of neutrophil and platelet engraftment, bacterial infections, viral reactivation, graft versus host disease, engraftment failure, relapse of underlying disease, and overall and disease-free survival.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements including statements regarding the therapeutic potential of PROHEMA®, the Company s clinical development plans for PROHEMA, and anticipated data and results from the Company s ongoing Phase 2 PUMA clinical trial. 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 PROHEMA observed in preclinical studies and clinical trials to date may not be replicated in the ongoing PUMA study or subsequent clinical trials of PROHEMA, the results observed in the PUMA study to date represent only interim results for a limited number of patients and final results may differ materially, PROHEMA 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-K for the year ended December 31, 2014 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: May 6, 2015

Fate Therapeutics, Inc.

By: /s/ J. Scott Wolchko
J. Scott Wolchko
Chief Financial Officer and Chief Operating Officer