

FATE THERAPEUTICS INC
Form 8-K
December 07, 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): December 7, 2015

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36076
(Commission

File Number)
3535 General Atomics Court, Suite 200

65-1311552
(I.R.S. Employer

Identification No.)

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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))

Item 8.01 Other Events.

On December 7, 2015, Fate Therapeutics, Inc. (the Company) announced interim data from the Company's Phase 2 PUMA clinical trial of ProHema® and provided an update on its therapeutic strategy for hematopoietic cell transplantation (HCT). The Company expects to file an investigational new drug application with the U.S. Food and Drug Administration in the next few weeks, and to initiate an open-label, randomized, controlled Phase 1/2 clinical trial of ProTmune in 2016, to investigate the potential of ProTmune to prevent acute graft-versus-host disease (GvHD) and severe viral infections in patients undergoing mobilized peripheral blood HCT. The Company is discontinuing further development of ProHema in patients undergoing cord blood HCT.

The open-label, randomized, controlled PUMA study was designed to assess ProHema in adult subjects undergoing cord blood HCT. Based on an October 15, 2015 data cut-off, an interim analysis of the PUMA study showed that subjects administered ProHema had an increase in the incidence of early neutrophil engraftment and a reduction in the incidence of severe viral infection-related adverse events (Grade 3-5) following HCT. Specifically, the analysis showed:

24 of 28 subjects administered ProHema achieved neutrophil engraftment. 16 of these 24 subjects (67%) achieved early neutrophil engraftment prior to a pre-specified historical control median time of engraftment (which has been established as Day 26 for subjects receiving myeloablative conditioning and Day 21 for subjects receiving reduced intensity conditioning). The overall reduction in the median time to neutrophil engraftment was 4.5 days, as compared to the applicable pre-specified historical control value.

14 of 15 concurrent control subjects achieved neutrophil engraftment. Eight of these 14 subjects (57%) achieved early neutrophil engraftment prior to the applicable pre-specified historical control median. The overall reduction in the median time to neutrophil engraftment was 2 days, as compared to the applicable pre-specified historical control value.

32% of subjects administered ProHema (9 of 28), as compared to 60% of concurrent control subjects (9 of 15), experienced one or more severe viral infection-related adverse events (Grade 3-5) following HCT; and, of the subjects who were cytomegalovirus (CMV)-seropositive at the time of HCT, 11% of subjects administered ProHema (2 of 18), as compared to 30% of concurrent control subjects (3 of 10), experienced one or more severe CMV-related adverse events (Grade 3-5) following HCT.

The Company is developing ProTmune, an adoptive immunotherapeutic programmed with two small molecules to prevent acute GvHD and severe viral infections while maintaining the cancer-fighting properties of donor mobilized peripheral blood (mPB) T cells. New preclinical data for ProTmune presented at the American Society of Hematology 2015 Annual Meeting show that a single administration of programmed mPB cells results in a statistically-significant reduction in GvHD score and improvement in survival as compared to vehicle-treated cells. The Company has also observed in preclinical models that the cancer-fighting properties of adoptively transferred programmed T cells are preserved.

About ProTmune

ProTmune is produced by modulating mobilized peripheral blood (mPB) *ex vivo* with two small molecules to enhance the immune tolerance and anti-infective activity of donor cells. Programmed mPB cells are adoptively transferred to a patient undergoing allogeneic HCT through a single administration. New preclinical data for ProTmune were presented at the American Society of Hematology 2015 Annual Meeting, demonstrating that programmed CD4+ and CD8+ T cells of mPB are functionally less allo-reactive. These data indicate a decrease in both the expression of costimulatory receptors and the production of pro-inflammatory cytokines, and an increase in the production of anti-inflammatory cytokines such as IL-10. Additionally, a single administration of programmed mPB cells showed a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, in preclinical models. The Company has also observed in preclinical models that the cancer-fighting properties of adoptively transferred programmed T cells are preserved.

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, including statements regarding the therapeutic potential of programmed cellular immunotherapeutics, including ProTmune, the Company's intention to initiate a clinical trial for ProTmune during 2016, the potential ability of ProTmune to reduce the incidence of acute GvHD and severe viral infections, and the Company's plans and ability to develop programmed cellular immunotherapeutics, including ProTmune. These and any other forward-looking statements in this release are based on management's current expectations of future events 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 risk of cessation or delay of planned development and clinical activities for a variety of reasons (including any adverse events or other results that may be observed during development), any inability to develop programmed cellular immunotherapeutics which are suitable for therapeutic applications, the risk that results observed in prior preclinical studies of ProTmune may not be replicated in subsequent studies or clinical trials, the risk that ProTmune or programmed cellular immunotherapeutics that the Company may develop may not produce therapeutic benefits or may cause other unanticipated adverse effects, and the risk that the Company may allocate its financial and other resources to programs or product candidates that ultimately have less therapeutic or commercial potential than other product candidates. 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, 2015, 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 7, 2015

Fate Therapeutics, Inc.

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