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): April 17, 2020

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))

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	FATE	Nasdaq Global Market

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 April 17, 2020, the U.S. Food and Drug Administration (FDA) allowed an Investigational New Drug (IND) application submitted by the Department of Medicine, Division of Infectious Diseases and International Medicine, University of Minnesota for the conduct of an investigator-initiated clinical trial "Study of FT516 Safety and Feasibility for the Treatment of Coronavirus Disease 2019 (COVID-19) in Hospitalized Patients with Hypoxia" (NCT04363346).

The open-label Phase 1 study is intended to investigate the clinical safety and tolerability of FT516, Fate Therapeutics, Inc.'s off-the-shelf natural killer (NK) cell product candidate derived from a clonal master induced pluripotent stem cell (iPSC) line engineered to express a novel CD16 Fc receptor, for the treatment of COVID-19 in up to 20 patients that are at a high risk of developing critical life-threatening illness. The clinical trial will enroll three dose cohorts evaluating three dosing strategies: (i) Dose Cohort 1 consisting of 90 million cells administered on Day 1; (ii) Dose Cohort 2 consisting of 90 million cells administered on Day 1 and 300 million cells administered on Day 4; and (iii) Dose Cohort 3 consisting of 90 million cells administered on Day 1, 300 million cells administered on Day 4, and 900 million cells administered on Day 7.

The study will proceed using an accelerated dose-escalation design, with one patient per dose cohort until the first dose-limiting toxicity (DLT) is observed, at which point the study will be conducted using a standard "3+3" dose-escalation design. If no DLT is observed, escalation will continue with one patient per dose cohort through Dose Cohort 3. Up to 10 patients may be treated in Dose Cohort 3.

The primary objective of the study is to determine the safety and maximum tolerated dose (MTD) of FT516 in hospitalized patients with hypoxia. Secondary objectives include time to elimination of viral shedding; time to discontinuation of supplemental oxygen support; and time to hospital discharge.

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: April 28, 2020

FATE THERAPEUTICS, INC.

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