

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): June 07, 2023

FATE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36076
(Commission File Number)

65-1311552
(IRS Employer
Identification No.)

12278 Scripps Summit Drive
San Diego, California
(Address of Principal Executive Offices)

92131
(Zip Code)

Registrant's Telephone Number, Including Area Code: 858 875-1800

(Former Name or Former Address, if Changed Since Last Report)

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, \$.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 Wednesday, June 7, 2023, Fate Therapeutics, Inc. (the “Company”) will present at the 2023 Jefferies Healthcare Conference. The presentation will provide a business update, including a regulatory and clinical update on its FT522 program.

The Company previously disclosed on May 3, 2023 that it had submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to investigate the safety and activity of FT522 in combination with CD20-targeted monoclonal antibody therapy in patients with relapsed / refractory B-cell lymphoma. The Company’s IND application has been allowed by the FDA, and the Company is currently conducting study start-up activities at multiple clinical sites.

The dose-escalating Phase 1 clinical trial is designed to assess a three-dose schedule of FT522 in each of two regimens:

- Regimen A – up to two treatment cycles, with each treatment cycle consisting of conditioning chemotherapy, a single dose of rituximab, and three doses of FT522.
- Regimen B – up to two treatment cycles, with each treatment cycle consisting of a single dose of rituximab and three doses of FT522 (without conditioning chemotherapy).

Patient enrollment into Regimen A will commence utilizing a three-dose schedule of FT522 at 300 million cells per dose. Subject to clearance of dose-limiting toxicities at this initial dose level of Regimen A, patient enrollment into Regimen B will then commence utilizing a three-dose schedule of FT522 at 300 million cells per dose. Dose escalation of each regimen may proceed independently.

Forward Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 including statements regarding the progress of and plans related to the Company’s product candidates, clinical studies, the therapeutic potential of the Company’s product candidates, the Company’s clinical and product development strategy, and the Company’s plans to initiate enrollment of each regimen in its dose-escalating Phase 1 clinical trial of FT522. 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 that the Company’s product candidates may not demonstrate the requisite safety or efficacy to warrant further development or to achieve regulatory approval, the risk that results observed in prior studies of the Company’s product candidates, including preclinical studies and clinical trials, will not be replicated in ongoing or future studies involving these product candidates, the risk of a delay or difficulties in the manufacturing of the Company’s product candidates or in the initiation and conduct of, or enrollment of patients in, any clinical trials, the risk that the Company may cease or delay preclinical or clinical development of any of its product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities on the initiation or conduct of clinical trials, changes in the therapeutic, regulatory, or competitive landscape for which the Company’s product candidates are being developed, the amount and type of data to be generated or otherwise to support regulatory approval, difficulties or delays in patient enrollment and continuation in the Company’s ongoing and planned clinical trials, difficulties in manufacturing or supplying the Company’s product candidates for clinical testing, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, 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 most recently filed periodic report, and from time to time in the Company’s press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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.

FATE THERAPEUTICS, INC.

Date: June 7, 2023

By: /s/ J. Scott Wolchko

J. Scott Wolchko
President and Chief Executive Officer
