
**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): September 25, 2026

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, \$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 September 25, 2026, the California Institute for Regenerative Medicine (“CIRM”) awarded Fate Therapeutics, Inc. (the “Company”) a \$15 million grant to support the Company’s Phase 2 RECLAIM-LN clinical trial of FT819. On September 25, 2026, the Company issued a press release announcing the award. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated September 25, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: September 28, 2026

By: /s/ Bahram Valamehr
Bahram Valamehr, Ph.D., MBA
President and Chief Executive Officer

Fate Therapeutics Announces Receipt of California Institute for Regenerative Medicine (CIRM) CLIN2 Grant to Advance RECLAIM-LN

\$15.0 Million Award to Support Advancement of RECLAIM-LN, a Phase 2 Potentially Registrational Trial of FT819 Off-the-Shelf CAR T-Cell Therapy in Lupus Nephritis

CLIN2 Grant is a highly competitive award from CIRM to fund advancing clinical trials for stem cell and gene therapies that have the potential to provide transformative benefits to patients and the healthcare system

SAN DIEGO, September 25, 2026 (GLOBE NEWSWIRE) – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to bringing a transformative pipeline of induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients with cancer and autoimmune diseases, today announced that the California Institute for Regenerative Medicine (CIRM) has awarded the Company a \$15.0 million grant, through its CLIN2 program, to support the clinical development of RECLAIM-LN, the Company's Phase 2, potentially registrational trial of FT819 off-the-shelf CAR T cell in patients with refractory moderate-to-severe Systemic Lupus Erythematosus (SLE) with Lupus Nephritis (LN).

“The CIRM Board’s award to Fate Therapeutics for its Phase 2 clinical trial of FT819 represents a significant step forward in transforming the clinical practice for patients living with a severe form of lupus,” said Sohel Talib, PhD, Senior Fellow in Clinical Development at CIRM. “This clinical study will evaluate the safety and efficacy of off-the-shelf immediately available CAR T-cell therapy with the ability to broaden the accessibility of this potentially curative therapy to patients who otherwise would not have access.”

LN is one of the most serious manifestations of SLE and a leading cause of morbidity and mortality among people living with the disease, affecting approximately 150,000 patients in the United States. Furthermore, there is a significant unmet need for patients that are refractory to the limited treatment options currently available. FT819 is designed to treat lupus by delivering deep and durable depletion of pathological B cells as an on-demand available CAR T-cell therapy that can be administered as outpatient treatment in the community setting, uniquely extending access beyond specialized treatment centers. Importantly, FT819 treatment may provide patients with the opportunity to discontinue standard therapies while significantly improving their quality of life, potentially providing refractory lupus patients with a chance to live a normal life.

“We appreciate CIRM identifying the urgent need for new options in refractory lupus and are honored that they have recognized the potential of FT819 off-the-shelf CAR T-cell therapy to treat large number of these patients in need, including in underserved regions,” said Bob Valamehr, President and Chief Executive Officer of Fate Therapeutics. “This prestigious grant by CIRM supports the continued advancement of RECLAIM-LN, our Phase 2 potentially registrational trial, and our commitment to making CAR T-cell therapy broadly accessible to patients living with this serious disease.”

CIRM's CLIN2 program is a competitive funding opportunity designed to advance clinical-stage product candidates that have the potential to become transformative therapies while also addressing barriers to patient access. The grant review is a multi-step process including detailed scientific evaluation conducted by expert panels. Beyond funding, CIRM devotes internal resources and leverages a network of world-class subject matter experts to help ensure funded projects have a comprehensive clinical development strategy aimed at obtaining marketing approval, with a well-developed plan for ensuring patient access.

About the RECLAIM-LN Phase 2 Clinical Trial

RECLAIM-LN (FT819-201; NCT07570862) is a multicenter Phase 2, open-label, single-arm trial designed to evaluate the efficacy and safety of FT819 in patients with refractory moderate-to-severe SLE with Class III or IV lupus nephritis (with or without concomitant class V). One of the most serious manifestations of SLE, lupus nephritis is a leading driver of kidney failure among patients with lupus, many of whom have exhausted available immunosuppressive treatment options. The study is expected to enroll approximately 53 patients who are refractory to at least two prior systemic immunosuppressive therapies. The primary endpoint is the proportion of participants achieving complete renal response (CRR) at Week 26. Key secondary endpoints include disease activity and quality of life measurements. Preliminary data from the Phase 1 study demonstrated favorable safety and tolerability and clinically meaningful improvement with sustained improvements across several disease activity measures, including clinical Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)-2K and urine protein-to-creatinine ratio (UPCr). Both measures showed further reductions with the use of less-intensive bendamustine conditioning.

The RECLAIM-LN study was developed through interactions with the FDA under FT819 Regenerative Medicine Advanced Therapy (RMAT) designation. FT819 has also been selected for the FDA's Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) program, which provides opportunities for early and enhanced communication with the FDA regarding CMC readiness for therapies with accelerated clinical development timelines.

About FT819

FT819 is an off-the-shelf CD19-targeting chimeric antigen receptor (CAR) T-cell product candidate engineered to improve safety and efficacy. Analogous to master cell banks used to mass produce biopharmaceutical drug products such as monoclonal antibodies, a precisely engineered clonal master induced pluripotent stem cell (iPSC) bank serves as the starting cell source to manufacture FT819, overcoming numerous limitations associated with patient- and donor-sourced CAR T-cell therapies. FT819 is well-defined and uniform in composition, produced at a low cost of goods, and can be stored in inventory for off-the-shelf, on-demand availability to enable access for a broad patient population. This research was additionally made possible by funding from the California Institute for Regenerative Medicine (CIRM), a state agency in California that supports research in

regenerative medicine, stem cell therapy, gene therapy, and clinical trials. (Grant number: CLIN2-16303) and (Grant number: CLIN2-20291)

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to bringing a pipeline of induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients. Using its proprietary iPSC product platform, the Company has established a leadership position in creating multiplexed-engineered iPSC lines and in the manufacture and clinical development of off-the-shelf, iPSC-derived cell products. The Company's pipeline includes iPSC-derived T-cell and natural killer (NK) cell product candidates, which are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple therapeutic mechanisms to patients. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements regarding the Company's product candidates, clinical studies and preclinical research and development programs, the Company's progress, plans and timelines for the clinical investigation of its product candidates, including the initiation and continuation of enrollment in the Company's clinical trials, the initiation of additional clinical trials, including in new indications, and additional dose cohorts in ongoing clinical trials of the Company's product candidates, the availability of data from the Company's clinical trials and the Company's plans to provide updates on its clinical trials, the therapeutic and market potential of the Company's research and development programs and product candidates, the Company's clinical and product development strategy, and the Company's progress and plans relating to, and the anticipated timing and outcome of, interactions with the FDA and other regulatory authorities. 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 research and development programs and product candidates, including those product candidates in clinical investigation, may not demonstrate the requisite safety, efficacy, or other attributes 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 observed 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, failure to demonstrate that a product candidate has the requisite safety, efficacy, or other attributes to warrant further development, and any adverse events or other negative results that may be observed during preclinical or clinical development), the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects, and risks relating to regulatory interactions and the outcome of such interactions. 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.

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