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): August 7, 2025

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)**	**(IRS Employer Identification No.)**

12278 Scripps Summit Dr. **San Diego, CA**	**92131**
(Address of principal executive office)	**(Zip Code)**

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

N/A
(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 2.02 Results of Operations and Financial Condition.

On August 12, 2025, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2025. A copy of the press release is attached as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On August 7, 2025, the Company's Board of Directors approved a corporate restructuring to streamline operations, reduce operating expenses, and extend cash runway (the "Restructuring"). In connection with the Restructuring, the Company committed to a reduction in total workforce by approximately 12% (the "RIF"). Affected employees were informed on August 12, 2025.

The Company expects the RIF to be completed during the third quarter of 2025, and estimates that it will incur charges of approximately $0.9 million to $1.2 million for severance and other employee termination-related costs during the third quarter of 2025. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the RIF. If the Company subsequently determines that it will incur additional significant costs associated with the RIF, it will amend this Current Report on Form 8-K to disclose such information.

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. Forward-looking statements can be identified by such words as "expect," "anticipate," "intend," "estimate," and words of similar import and are based on current expectations that involve risks and uncertainties, such as the Company's plans, objectives, expectations and intentions. All statements other than historical or current facts are forward-looking statements, including, without limitation, statements about the expected timing, magnitude and financial impact of the Restructuring and the RIF, anticipated extension of the Company's cash runway, and the terms and conditions associated with the termination of employees. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially and adversely from those anticipated in the forward-looking statements. The statements in this Current Report on Form 8-K, including all forward-looking statements, speak only as of the date of this report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated August 12, 2025
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.

Date: August 12, 2025

FATE THERAPEUTICS, INC.

By: /s/ Bahram Valamehr
Bahram Valamehr, Ph.D., M.B.A.
President and Chief Executive Officer

Exhibit 99.1

Fate Therapeutics Reports Second Quarter 2025 Financial Results and Business Updates

First patient treated with FT819 off-the-shelf CAR T-cell product candidate following fludarabine-free conditioning for severe lupus nephritis demonstrated durability of response with drug-free definition of remission in systemic lupus erythematosus (DORIS) at 12-month follow-up

Held initial discussion with FDA under FT819 RMAT designation to seek feedback on registrational pathway in moderate-to-severe Systemic Lupus Erythematosus (SLE) and refractory Lupus Nephritis (LN)

First extrarenal SLE patient treated with FT819 in the absence of conditioning, and as add-on to standard-of-care maintenance therapy, achieved Low Lupus Disease Activity State (LLDAS) at 3- and 6-month follow-up

IND application allowed by FDA for FT836 MICA/B-targeted off-the-shelf CAR T cell with Sword and Shield™ technology for conditioning-free treatment of broad array of solid tumors

Projected operating runway extended through YE27 to enable achievement of key clinical and collaboration milestones with $249 million in cash, cash equivalents, and investments

San Diego, August 12, 2025 — Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of induced pluripotent stem cell (iPSC)-derived off-the-shelf cellular immunotherapies to patients, today reported business highlights and financial results for the second quarter ended June 30, 2025.

“We begin the second half of the year with meaningful progress across our clinical programs as we continue our mission to make cell therapies accessible to all. Our priority remains focused on driving patient enrollment to demonstrate both the therapeutic differentiation and unique on-demand availability of FT819 in autoimmune diseases. We remain encouraged by the promising FT819 data in SLE and LN we reported this past quarter, showing significant disease improvement with less-intensive or no conditioning, and have made strides in expanding our trial sites and accelerating enrollment. Building on this momentum, we are also working closely with the FDA under our RMAT designation with the goal of commencing our registrational study for FT819 in SLE and LN in 2026,” said Bob Valamehr, Ph.D., MBA, President and Chief Executive Officer of Fate Therapeutics. “Additionally, we continue to strengthen our broader pipeline programs with an extended partnership with Ono Pharmaceuticals, and advancements in bringing our next-generation, off-the-shelf CAR T cells with Sword and Shield™ technology toward the clinic. Operationally, we have taken proactive steps to optimize our resource allocation and extend our cash runway, positioning us well to continue executing across our pipeline, working to bring transformative off-the-shelf cellular immunotherapies to patients with unmet needs.”

FT819 iPSC-derived off-the-shelf CAR T-cell program in autoimmune disease

- **In discussion with the FDA on potential registrational study design in moderate-to-severe SLE and refractory LN.** In August, the Company met with the U.S. Food and Drug Administration (FDA) under its Regenerative Medicine Advanced Therapy (RMAT) designation for FT819 to seek preliminary feedback on a proposed registrational study design to support regulatory approval in moderate-to-severe SLE and refractory LN. In April 2025, the Company was granted RMAT designation by the FDA for FT819 to treat moderate-to-severe SLE, including LN. Established under the 21st Century Cures Act, the RMAT designation program was created to expedite the development and review of regenerative medicine therapies for serious or life-threatening diseases or conditions.
- **Interim Phase 1 SLE data using fludarabine-free conditioning regimen presented at EULAR congress and patient enrollment ongoing.** The Phase 1 clinical trial of FT819 for the treatment of patients with moderate-to-severe SLE, including patients with LN and with extrarenal lupus (NCT06308978), continues enrolling patients at two dose levels – a single dose of 360 million cells and a single dose of 900 million cells. The Company intends to identify a recommended dose for a registration enabling study and continues to expand clinical site activation in the U.S. and entry into European Union and United Kingdom to broaden geographic reach. At the European Alliance of Associations for Rheumatology (EULAR) 2025 Congress in June, interim Phase 1 data from patients with moderate-to-severe SLE with or without LN using a fludarabine-free conditioning regimen was presented. Three patients with refractory active LN (median prior therapies = 8 [7-8]) were treated with a single dose of FT819 at 360 million cells following a fludarabine (flu)-free conditioning regimen. As of the data cut-off date of May 15, 2025, all three patients achieved an objective renal response. The first LN patient achieved DORIS as well as complete renal response at 6 months, which was also noted at 12-month follow up. Additionally, one patient with refractory extrarenal lupus (prior therapies = 6, including cyclophosphamide; SLEDAI-2K = 18) was treated with a single dose of FT819 at 900 million cells and a single dose of cyclophosphamide. The patient was evaluable for 1-month follow-up, demonstrating improvement across multiple disease-specific scores including an 8-point reduction in SLEDAI-2K from baseline and a 1-point reduction in physician's global assessment (PGA).
- **First SLE patient treated as add-on to standard-of-care maintenance therapy.** The Company's Phase 1 SLE study is also designed to assess the safety, pharmacokinetics, and anti-B cell activity of FT819 as an add-on to maintenance therapy without conditioning chemotherapy. At the EULAR Congress in June, the Company reported that the first patient treated while on maintenance therapy, a stable dose of mycophenolate mofetil and steroids for the treatment of refractory extrarenal lupus, received a single dose of FT819 at 360 million cells as an add-on to maintenance therapy (prior therapies = 5). As of the data cut-off date of May 15, 2025, the patient achieved low lupus disease activity state (LLDAS) at 3- and 6-months following administration of FT819 in the absence of conditioning. The patient also experienced a reduction in SLEDAI-2K to 2 from 8 at baseline and in PGA to 0.5 from 2 at baseline, with tapering of steroid dose to less than 5 mg / day. Patient enrollment is ongoing with the aim of investigating patient outcome with single- or multiple-doses of FT819 within a treatment cycle.

- **Phase 1 SLE study amended to include additional B cell-mediated autoimmune diseases.** The Company has expanded its current Phase 1 clinical trial of FT819 to include clinical investigation of multiple B cell-mediated autoimmune diseases, with plans to initiate independent dose-expansion cohorts in the second half of 2025 for the treatment of anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV), idiopathic inflammatory myositis (IIM), and systemic sclerosis (SSc).

FT825 / ONO-8250 iPSC-derived off-the-shelf CAR T-cell Program in Solid Tumors

- **Phase 1 study ongoing for advanced solid tumors.** Under its collaboration with Ono Pharmaceutical Co., Ltd. (Ono), the Company is conducting a multi-center, Phase 1 study to assess the safety, pharmacokinetics, and activity of FT825 / ONO-8250, a multiplex-engineered CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2), in patients with advanced solid tumors (NCT06241456). The study now includes fresh-biopsy testing for HER2 expression to ensure patient stratification and eligibility based on HER2 status. Dose escalation is currently ongoing at the third dose level of 900 million cells, with each patient administered conditioning chemotherapy and a single dose of FT825 / ONO-8250 either as monotherapy or in combination with epidermal growth factor receptor (EGFR)-targeted monoclonal antibody therapy. FT825 / ONO-8250 has demonstrated a favorable safety profile with no dose-limiting toxicities (DLTs) to date.

Next-generation iPSC-derived off-the-shelf CAR T-cell Programs with Novel Sword & Shield™ Technology Designed to Reduce or Eliminate the Need for Conditioning Chemotherapy

- **IND allowance by FDA for FT836 MICA/B-targeted CAR T-cell program.** In July, the FDA allowed the Company's investigational new drug (IND) application to initiate Phase 1 clinical testing of FT836, a multiplex-engineered CAR T-cell product candidate uniquely targeting major histocompatibility complex (MHC) proteins A (MICA) and B (MICB) which are expressed on many types of cancer cells with limited detection on healthy tissue. The Phase 1 study is designed to assess the safety and activity of FT836 without administration of conditioning chemotherapy for the treatment of advanced solid tumors. The development of FT836 is supported by a $4 million award from the California Institute of Regenerative Medicine (CIRM).
- **Creation of master iPSC bank for FT839 dual-CAR T-cell program.** FT839 is a CD19/CD38 dual CAR T-cell product candidate designed to target an array of aberrant immune cells. At the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting in May, the Company presented preclinical data demonstrating robust eradication of aberrant CD19+ B cells, CD38+ plasma cells, and CD38+ activated T cells by FT839 using unmatched peripheral blood mononuclear cells sourced from a patient with autoimmune disease. The Company has generated a master iPSC bank for conduct of further preclinical and IND-enabling studies, and is currently evaluating opportunities for clinical investigation of FT839 in hematological malignancies and autoimmunity, beginning in 2026.

Other Corporate Updates

- **Extension of Ono collaboration for second solid tumor CAR T-cell product candidate.** Under its collaboration with Ono, the Company is conducting preclinical development of a second iPSC-derived CAR T-cell candidate targeting an undisclosed solid tumor antigen. Based on a review of the preclinical data package for the collaboration candidate in June, the Company and Ono agreed to extend the collaboration's research term and continue further preclinical development of the candidate. The Company expects to continue to receive co-funding from Ono in connection with its preclinical development activities under the joint research plan through at least June 2026.
- **Operating runway extension.** The Company has implemented a tactical operations plan that is expected to extend funding of its operations through the end of 2027, which is intended to enable the achievement of key clinical and collaboration milestones while maintaining sufficient funds to support ongoing operations beyond those milestones. The cash runway extension includes the pipeline prioritization of its iPSC-derived CAR T-cell programs, a 12% reduction in its current employee headcount, and cost saving measures across the organization.

Second Quarter 2025 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents, and investments as of June 30, 2025 were $248.9 million.
- **Total Revenue:** Revenue was $1.9 million for the second quarter of 2025, which was derived from the conduct of preclinical development activities for a second collaboration candidate targeting an undisclosed solid tumor antigen under the Company's collaboration with Ono Pharmaceutical.
- **Total Operating Expenses:** Total operating expenses were $38.9 million for the second quarter of 2025, including research and development expenses of $27.4 million and general and administrative expenses of $11.4 million. Such amount included $7.2 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** As of June 30, 2025, common shares outstanding were 114.7 million, pre-funded warrants outstanding were 3.9 million, and preferred shares outstanding were 2.8 million. Each preferred share is convertible into five common shares.

About Fate Therapeutics' iPSC Product Platform

Human induced pluripotent stem cells (iPSCs) possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's proprietary iPSC product platform combines multiplexed-engineering of human iPSCs with single-cell selection to create clonal master iPSC lines. Analogous to master cell lines used to mass produce biopharmaceutical drug products such as monoclonal antibodies, the Company utilizes its clonal master iPSC lines as a starting cell source to manufacture engineered cell products which are well-defined and uniform in composition, can be stored in inventory for off-the-shelf availability, can be administered in combination with other therapies, and can potentially reach a broad patient population. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with patient- and donor-sourced cell therapies. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 500 issued patents and 500 pending patent applications.

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 master 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 results of operations, financial condition, anticipated operating expenses and cash runway, and sufficiency of its cash and cash equivalents to fund its operations, as well as statements regarding the advancement of and plans related to 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 Company's plans to complete IND-enabling studies and to submit IND applications for its product candidates, 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 expectations regarding progress and timelines, the objectives, plans and goals of its collaboration with Ono, and the Company's expectations regarding the receipt of funding under the collaboration and

the expected effects of the Company's pipeline prioritization plan and reduction in force. 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, the risk that the Company may not comply with its obligations under and otherwise maintain its collaboration agreement with Ono, the risk that research funding and milestone payments received by the Company under its collaboration may be less than expected, and the risk that the Company may incur operating expenses in amounts greater than anticipated. 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.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 1,907	$ 6,772	$ 3,536	$ 8,697
Operating expenses:				
Research and development	27,430	34,604	56,566	66,742
General and administrative	11,445	17,251	25,218	38,106
Total operating expenses	38,875	51,855	81,784	104,848
Loss from operations	(36,968)	(45,083)	(78,248)	(96,151)
Other income (expense):				
Interest income	2,921	4,827	6,257	8,976
Change in fair value of stock price appreciation milestones	(73)	1,556	207	162
Other income	50	273	93	582
Total other income	2,898	6,656	6,557	9,720
Net loss	$ (34,070)	$ (38,427)	$ (71,691)	$ (86,431)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(129)	(228)	(206)	(437)
Comprehensive loss	$ (34,199)	$ (38,655)	$ (71,897)	$ (86,868)
Net loss per common share, basic and diluted	$ (0.29)	$ (0.33)	$ (0.61)	$ (0.79)
Weighted-average common shares used to compute basic and diluted net loss per share	118,528,046	117,468,124	118,452,214	109,286,235

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 41,249	$ 36,056
Accounts receivable	1,395	3,539
Short-term investments	181,581	243,012
Prepaid expenses and other current assets	6,172	9,302
Total current assets	230,397	291,909
Long-term investments	26,097	27,657
Operating lease right-of-use asset	43,814	46,508
Other long-term assets	71,324	74,620
Total assets	$371,632	$ 440,694
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,222	$ 30,713
CIRM award liability, current portion	795	—
Deferred revenue	—	393
Operating lease liability, current portion	5,656	7,416
Total current liabilities	28,673	38,522
CIRM award liability, net of current portion	5,600	5,070
Operating lease liability, net of current portion	75,675	77,849
Stock price appreciation milestones	320	527
Stockholders' equity	261,364	318,726
Total liabilities and stockholders' equity	$371,632	$ 440,694

Contact:
Christina Tartaglia
Precision AQ
212.362.1200
christina.tartaglia@precisionaq.com