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): March 05, 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 Drive San Diego, California	**92131**
(Address of Principal Executive Offices)	**(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 2.02 Results of Operations and Financial Condition.

On March 5, 2025, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2024. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated March 5, 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 thereunto duly authorized.

FATE THERAPEUTICS, INC.

Date: March 5, 2025

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

Exhibit 99.1

Fate Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Business Updates

Phase 1 Dose Expansion Initiated for FT819 Off-the-Shelf CAR T-cell Product Candidate with Fludarabine-free Conditioning in Moderate-to-Severe SLE

Completed Type D Meeting with FDA to Enable FT819 Off-the-Shelf CAR T-cell Dose Expansion in Additional B Cell-mediated Autoimmune Diseases

First FT819 Off-the-Shelf CAR T-cell Patient Treated without Conditioning Chemotherapy as Add-on to Maintenance Therapy in SLE

$307 Million in Cash, Cash Equivalents and Investments with Projected Operating Runway through YE26

San Diego, March 5, 2025 -- Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to bringing a pipeline of induced pluripotent stem cell (iPSC)-derived off-the-shelf cellular immunotherapies to patients, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2024.

"We begin 2025 with resolve and focus to advance our lead clinical programs in autoimmunity and oncology," said Bob Valamehr, Ph.D. MBA, President and Chief Executive Officer of Fate Therapeutics. "The team continues to make great progress in our pursuit of achieving therapeutic differentiation for patients with B cell-mediated autoimmune diseases, and we look forward to providing clinical and regulatory updates as we advance our FT819 off-the-shelf CAR T-cell product candidate in SLE. We remain focused on driving patient enrollment and engaging with the FDA to further discuss novel development pathways for CAR T-cell therapy in autoimmune disease, including the use of fludarabine-free conditioning as well as add-on to maintenance therapy without conditioning. We also plan to explore FT819 clinical trial expansion in additional autoimmune diseases. In addition, our FT825 off-the-shelf CAR T-cell program for advanced solid tumors is advancing into higher-dose cohorts as monotherapy and in combination with monoclonal antibody therapy under our collaboration with Ono Pharmaceutical. We look forward to sharing clinical data from these two high-priority programs throughout the year."

FT819 iPSC-derived 1XX CAR T-cell Program

- **Phase 1 Dose Expansion Initiated for SLE using Flu-free Conditioning Regimen.** Based on clinical data from the first three patients treated with FT819 in its ongoing multi-center, Phase 1 clinical trial for moderate-to-severe systemic lupus erythematosus (SLE) (NCT06308978), the Company has initiated dose expansion in up to 10 patients at 360 million cells. The dose expansion stage is designed to evaluate the safety and efficacy of a fludarabine (flu)-free conditioning regimen, consisting of either bendamustine alone or cyclophosphamide alone, followed by a single dose of

FT819. The Company is also assessing the safety, pharmacokinetics, and anti-B cell activity of FT819 at 900 million cells in dose escalation. FT819 is the Company's off-the-shelf CD8αβ+ T-cell product candidate that incorporates a CD19-targeted chimeric antigen receptor (CAR) with a novel 1XX costimulatory domain into the T-cell receptor alpha constant (TRAC) locus.

- **Clinical Data from First Three SLE Patients Presented at ASH.** In December 2024, the Company highlighted clinical and translational data from the first three patients treated with FT819 for SLE at the American Society of Hematology (ASH) Annual Meeting. Each patient presented with active lupus nephritis (LN) despite having been treated with multiple standard-of-care therapies and received flu-free conditioning followed by a single dose of FT819 at 360 million cells. As of a data cutoff date of December 4, 2024, there were no dose-limiting toxicities (DLTs), and no events of any grade of cytokine release syndrome (CRS), immune effector-cell associated neurotoxicity syndrome (ICANS), or graft-versus-host disease (GvHD). All three patients showed rapid, deep, and sustained elimination of CD19+ B cells in the periphery during the first month of treatment. The first and only patient eligible for disease assessment at six-month follow-up as of the data cutoff date achieved DORIS (Definition Of Remission In SLE) clinical remission and was free of all immunosuppressive therapy.
- **First Patient Treated with FT819 as Add-on to Maintenance Therapy.** The Company amended the clinical protocol of its FT819 Phase 1 study to include a new treatment arm to assess the safety, pharmacokinetics, and anti-B cell activity of a single dose of FT819 as an add-on to maintenance therapy without conditioning chemotherapy in patients with SLE. The first patient in the new arm was on a stable dose of oral mycophenolate mofetil (MMF) and was treated with a single dose of FT819 at 360 million cells without administration of any conditioning chemotherapy. There were no DLTs and no events of CRS, ICANS, or GvHD. The patient remains on-study.
- **Completed Type D Meeting with FDA for Inclusion of Additional Diseases in FT819 Phase 1 Study.** In December 2024, the Company reached an agreement with the U.S. Food and Drug Administration (FDA) to allow for the clinical investigation of additional B cell-mediated autoimmune diseases under our current Phase 1 clinical trial of FT819. As a follow-up to the meeting, the Company has submitted an amended clinical protocol to the FDA that enables the conduct of independent dose-expansion cohorts for SLE as well as anti-neutrophilic cytoplasmic antibody-associated vasculitis (AAV), idiopathic inflammatory myositis (IIM), and systemic sclerosis (SSc). The Company plans to initiate dose-expansion cohorts in one or more of AAV, IIM, and SSc in 2025. Additionally, the FDA agreed to allow for investigation of a multi-dose treatment cycle as well as for re-treatment upon disease progression, making the treatment dosing paradigm more aligned with traditional biological therapies. The FDA also permitted the expansion of study eligibility criteria, including the inclusion of patients between the ages of 12 and 17.

FT825 / ONO-8250 iPSC-derived CAR T-cell Program

- **First Patient Treated with FT825 / ONO-8250 in Combination with Monoclonal Antibody Therapy.** 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 multiplexed-engineered CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2), in patients with advanced solid tumors (NCT06241456). Enrollment is currently ongoing at the third dose level of 900 million cells as monotherapy and at the second dose level of 300 million cells in combination with epidermal growth factor receptor (EGFR)-targeted monoclonal antibody therapy.
- **Initial Phase 1 Clinical Data Presented at 2024 SITC.** At the 2024 Society of Immunotherapy of Cancer (SITC) in November, the Company presented initial clinical data from three heavily

pre-treated patients, all of whom were previously treated with at least five prior lines of therapy including HER2-targeted therapy. Each patient was administered conditioning chemotherapy and a single dose of FT825 / ONO-8250 as monotherapy at the first dose level of 100 million cells. As of a data cutoff date of October 25, 2024, FT825 / ONO-8250 demonstrated a favorable safety profile with no DLTs and no events of any grade of CRS, ICANS, or GvHD. In addition, at Day 8 following treatment, peak CAR T-cell expansion was observed and phenotyping of FT825 / ONO-8250 sourced from the patients' peripheral blood was indicative of an activated state (as evidenced by high levels of Granzyme B expression and maintenance of CAR expression) with no evidence of exhaustion (as evidenced by low levels of PD-1 and TIM3 expression).

FT522 iPSC-derived CAR NK Cell Program

- **Initial Translational Data of FT522 without Conditioning Chemotherapy Presented at ACR Convergence.** FT522 is the Company's off-the-shelf, CD19-targeted CAR NK cell product candidate and first product candidate to incorporate Alloimmune Defense Receptor (ADR) technology, which is designed to reduce or eliminate the need for administration of conditioning chemotherapy to patients receiving cell therapies. In November 2024, the Company presented initial translational data from its ongoing multi-center, Phase 1 clinical trial of FT522 in patients with relapsed / refractory B-cell lymphoma (BCL) (NCT05950334). The presentation illustrated that live FT522 cells with anti-B cell activity were detected in the patients' peripheral blood through Day 15, demonstrating the potential of FT522 to persist and function in the presence of an unmatched, fully-intact immune system. The Company intends to assess any further clinical development of FT522 in relapsed / refractory BCL upon completion of dose escalation at the second dose level of 900 million cells.
- **Unique Clinical Development Opportunities for FT522 in Autoimmunity under Evaluation.** The FDA has allowed the Company's Investigational New Drug (IND) application to assess the safety, pharmacokinetics, and activity of FT522 across a basket of B cell-mediated autoimmune diseases. The Phase 1 clinical protocol allows for treatment of patients with up to four weekly doses of FT522, without administration of conditioning chemotherapy, as an add-on to rituximab induction therapy (Regimen A) and as an add-on to maintenance therapy in combination with rituximab (Regimen B). The Company is currently evaluating opportunities and timelines for the clinical development of FT522 in autoimmunity.

Fourth Quarter 2024 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents, and investments as of December 31, 2024 were $306.7 million.
- **Total Revenue:** Revenue was $1.9 million for the fourth quarter of 2024, 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 $63.6 million for the fourth quarter of 2024, including research and development expenses of $33.6 million and general and administrative expenses of $15.3 million. Such amount included $9.1 million of non-cash stock-based compensation expense and a one-time non-cash asset impairment charge of $14.7 million related to equipment and right-of-use assets.
- **Shares Outstanding:** As of December 31, 2024, common shares outstanding were 113.9 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 first-in-class 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, and the objectives, plans and goals of its collaboration with Ono. 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 or from CIRM 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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Collaboration revenue	$ 1,860	$ 1,676	$ 13,631	$ 63,533
Operating expenses:				
Research and development	33,609	31,816	135,001	172,596
General and administrative	15,262	17,935	74,169	81,448
Impairment loss	14,737	—	14,737	—
Total operating expenses	63,608	49,751	223,907	254,044
Loss from operations	(61,748)	(48,075)	(210,276)	(190,511)
Other income (expense):				
Interest income	3,874	4,414	17,288	17,186
Change in fair value of stock price appreciation milestones	670	(645)	819	2,515
Other income	5,051	184	5,907	9,882
Total other income (expense), net	9,595	3,953	24,014	29,583
Net loss	$ (52,153)	$ (44,122)	$ (186,262)	$ (160,928)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities, net	(567)	514	253	1,869
Comprehensive loss	$ (52,720)	$ (43,608)	$ (186,009)	$ (159,059)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.45)	$ (1.64)	$ (1.64)
Weighted–average common shares used to compute basic and diluted net loss per share	117,794,424	98,613,726	113,685,177	98,411,162

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 36,056	$ 41,870
Accounts receivable	3,539	1,826
Short-term investments	243,012	273,305
Prepaid expenses and other current assets	9,302	14,539
Total current assets	291,909	331,540
Long-term investments	27,657	980
Operating lease right-of-use asset	46,508	61,675
Other long-term assets	74,620	112,022
Total assets	$ 440,694	$ 506,217
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 30,713	$ 32,233
Deferred revenue	393	685
Operating lease liability, current portion	7,416	6,176
Total current liabilities	38,522	39,094
CIRM award liability	5,070	—
Operating lease liability, net of current portion	77,849	97,360
Stock price appreciation milestones	527	1,346
Stockholders' equity	318,726	368,417
Total liabilities and stockholders' equity	$ 440,694	$ 506,217

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