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 13, 2024

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 August 13, 2024, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 13, 2024
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: August 13, 2024

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

Exhibit 99.1

Fate Therapeutics Reports Second Quarter 2024 Financial Results and Business Updates

Enrollment Ongoing with FT819 1XX CAR T-cell Product Candidate in Phase 1 Autoimmunity Study; Single-agent Cyclophosphamide Included as Alternative Conditioning Regimen

First Patient Treated with FT522 CAR NK Cell Product Candidate in Conditioning-free Arm of Phase 1 B Cell Lymphoma Study

FT522 Multi-indication IND Application for Conditioning-free Treatment of Autoimmune Diseases to be Submitted in 3Q24

Enrollment Ongoing with FT825 / ONO-8250 CAR T-cell Product Candidate as Monotherapy in Phase 1 Solid Tumor Study; Dosing in Combination with Monoclonal Antibody Therapy Expected to Initiate in 3Q24

$352 Million in Cash, Cash Equivalents, and Investments with Projected Operating Runway through YE26

San Diego, CA – August 13, 2024 – 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 cellular immunotherapies to patients with cancer and autoimmune diseases, today reported business highlights and financial results for the second quarter ended June 30, 2024.

“We are pleased with the initial clinical and translational observations from our three ongoing Phase 1 studies and look forward to sharing data from each program in the second half of 2024,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We remain keenly focused on achieving therapeutic differentiation in autoimmunity with our off-the-shelf FT819 CAR T-cell and FT522 CAR NK cell product candidates. Our ongoing FT819 study for systemic lupus erythematosus now includes single-agent cyclophosphamide as an alternative conditioning regimen for patients, and we are working to expand clinical investigation of FT819 to treat additional B cell-mediated diseases. We are also finalizing our FT522 IND submission for the treatment of a basket of autoimmune diseases without administration of conditioning chemotherapy to patients, having now treated the first patient without conditioning chemotherapy in our ongoing FT522 study for B cell lymphoma. In addition, under our solid tumor collaboration with Ono Pharmaceutical, we have now treated the first three patients as monotherapy with our multiplexed-engineered FT825 CAR T-cell collaboration candidate, and we are poised to initiate dosing in combination with monoclonal antibody therapy to explore the potential of dual-antigen targeting in advanced solid tumors.”

FT819 iPSC-derived 1XX CAR T-cell Program

- **Enrollment Ongoing in FT819 Phase 1 Autoimmunity Study.** The multi-center, Phase 1 clinical trial for patients with systemic lupus erythematosus (SLE) is designed to evaluate the safety, pharmacokinetics, and anti-B cell activity of FT819, 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 (NCT06308978). The first patient treated in the study, a 27 year-old woman diagnosed with lupus nephritis over ten years ago who has refractory disease despite having been treated with multiple standard-of-care therapies, received conditioning chemotherapy followed by a single dose of FT819 at 360 million cells. The patient remains on-study, and there have been no Grade ≥3 adverse events and no events of any grade of cytokine release syndrome (CRS), immune effector-cell associated neurotoxicity syndrome (ICANS), or graft-versus-host disease (GvHD). The Company plans to present clinical and translational data from the Phase 1 study at a medical conference in the second half of 2024.
- **Single-agent Cyclophosphamide Included as Alternative Conditioning Regimen.** In addition to conditioning of patients with either cyclophosphamide and fludarabine (Cy / Flu) or bendamustine, the Company amended the clinical protocol of its FT819 Phase 1 autoimmunity study to include single-agent cyclophosphamide (Cy) as a third conditioning regimen. Cy is a commonly-used agent with an established safety profile for the treatment of patients with B cell-mediated autoimmune diseases.
- **Favorable Safety Profile and Proof-of-Concept for Autoimmune Disease Established in FT819 Phase 1 BCM Study.** At the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting in May, the Company presented clinical and translational data from its FT819 Phase 1 study in relapsed / refractory B cell malignancies (BCM) (NCT04629729). 43 heavily pre-treated patients were treated with conditioning chemotherapy and a single dose of FT819 across five dose levels. The safety and tolerability profile of FT819 was favorable, with no dose-limiting toxicities, no events of any grade of ICANS or GvHD, and low incidence (14%) of low-grade CRS. In addition, a single dose of FT819 exhibited multiple mechanisms implicated in generating an immune reset in patients with B cell-mediated autoimmune diseases, including rapid, deep, and sustained CD19+ B-cell depletion in the periphery throughout the one-month treatment cycle as well as primary, secondary, and tertiary tissue trafficking, infiltration, and activity with CD19+ B cell elimination in tissue. The Company successfully completed dose escalation in its FT819 Phase 1 BCM study, and has focused further clinical development of FT819 exclusively in autoimmunity.

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

- **Enrollment Ongoing in Phase 1 Study with HER2-targeted CAR T-cell 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 as monotherapy and in combination with monoclonal antibody therapy in patients with advanced solid tumors (NCT06241456). Designed using the Company's iPSC product platform, FT825 / ONO-8250 incorporates seven synthetic controls of cell function including a novel cancer-specific H_2CasMab-2 CAR, which has exhibited similar potency with greater specificity for cancer cells expressing HER2 compared to trastuzumab in preclinical studies. Three patients have been treated in the Phase 1 study with a single dose of FT825 / ONO-8250 as monotherapy at the first dose level of 100 million cells and, during the third quarter of 2024, the Company plans to initiate enrollment as monotherapy at the second dose level of 300 million cells and in combination with epidermal growth factor receptor (EGFR)-targeted monoclonal antibody therapy at the first

dose level of 100 million cells. The Company plans to present clinical and translational data from the Phase 1 study at a medical conference in the second half of 2024.

FT522 iPSC-derived CAR NK Cell Program

- **First Patient Treated without Conditioning in Phase 1 BCL Study.** FT522 is the Company's off-the-shelf, CD19-targeted CAR NK cell product candidate and its first 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 its ongoing multi-center, Phase 1 clinical trial of FT522 in patients with relapsed / refractory B-cell lymphoma (BCL) (NCT05950334), the first patient has now been treated in the first three-dose cohort at 300 million cells per dose without conditioning chemotherapy (Regimen B). In addition, the first patient has now been treated in the second three-dose cohort at 900 million cells per dose with conditioning chemotherapy (Regimen A). No dose-limiting toxicities and no events of any grade of CRS, ICANS, or GvHD, have been reported in the Phase 1 study. The Company plans to present clinical and translational data from the Phase 1 study at a medical conference in the second half of 2024.
- **IND Application for Phase 1 Basket Study in Autoimmunity to be Submitted in 3Q24.** The Company intends to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in the third quarter of 2024 for the treatment of a basket of B cell-mediated autoimmune diseases with FT522, including without administration of conditioning chemotherapy to patients. At the ASGCT conference, the Company presented preclinical data from a novel re-challenge assay using peripheral blood mononuclear cells (PBMCs) from unmatched SLE donors, showing that FT522 uniquely drove rapid and deep CD19+ B cell depletion, eliminated alloreactive T cells, and maintained functional persistence, indicating that FT522 can function effectively in the presence of an unmatched host immune system. The Company also shared initial clinical observations from the first two patients treated with FT522 at 100 million cells per dose in Regimen A of its ongoing Phase 1 BCL study, which showed rapid, deep, and sustained B-cell depletion in the periphery throughout the one-month treatment cycle. In addition, both patients showed enhanced persistence of FT522 in the periphery compared to clinical data observed with FT596, a prior-generation CD19-targeted CAR NK cell without ADR technology.

Second Quarter 2024 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of June 30, 2024 were $352.0 million.
- **Total Revenue:** Revenue was $6.8 million for the second quarter of 2024, which was derived from the achievement of a $5 million milestone in connection with the clinical development of FT825 / ONO-8250 and the conduct of preclinical development activities for a second collaboration candidate targeting an undisclosed solid tumor antigen under its collaboration with Ono.
- **Total Operating Expenses:** For the second quarter of 2024, GAAP operating expenses were $51.9 million, including research and development expenses of $34.6 million and general and administrative expenses of $17.3 million. Such amounts included $9.6 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 113.8 million, pre-funded warrants outstanding were 3.9 million, and preferred shares outstanding were 2.8 million, as of June 30, 2024. 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 combined and administered 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 the manufacture of cell therapies using patient- or donor-sourced cells. 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 with cancer and autoimmune diseases. 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 natural killer (NK) cell and T-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 initiation and continuation of enrollment in the Company's clinical trials, the initiation of additional clinical trials and additional dose cohorts in ongoing clinical trials of the Company's product candidates, the availability of data from the Company's clinical trials, the Company's plans to submit additional IND applications for its product candidates and the timing thereof, 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 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,	
	2024	2023	2024	2023
Collaboration revenue	$ 6,772	$ 933	$ 8,697	$ 59,913
Operating expenses:				
Research and development	34,604	40,876	66,742	106,505
General and administrative	17,251	22,622	38,106	44,565
Total operating expenses	51,855	63,498	104,848	151,070
Loss from operations	(45,083)	(62,565)	(96,151)	(91,157)
Other income (expense):				
Interest income	4,827	4,381	8,976	8,075
Change in fair value of stock price appreciation milestones	1,556	393	162	2,111
Other Income	273	5,036	582	9,335
Total other income (expense), net	6,656	9,810	9,720	19,521
Net loss	$ (38,427)	$ (52,755)	$ (86,431)	$ (71,636)
Other comprehensive income (loss):				
Unrealized (loss) gain on available-for-sale securities, net	(228)	59	(437)	1,267
Comprehensive loss	$ (38,655)	$ (52,696)	$ (86,868)	$ (70,369)
Net loss per common share, basic and diluted	$ (0.33)	$ (0.54)	$ (0.79)	$ (0.73)
Weighted–average common shares used to compute basic and diluted net loss per share	117,468,124	98,400,355	109,286,235	98,228,476

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 36,917	$ 41,870
Accounts receivable	1,048	1,826
Short-term investments	267,962	273,305
Prepaid expenses and other current assets	13,461	14,539
Total current assets	319,388	331,540
Long-term investments	47,162	980
Operating lease right-of-use asset	59,547	61,675
Other long-term assets	102,720	112,022
Total assets	$ 528,817	$ 506,217
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 28,149	$ 32,233
Deferred revenue	—	685
Operating lease liability, current portion	6,644	6,176
Total current liabilities	34,793	39,094
CIRM award liability	1,940	—
Operating lease liability, net of current portion	93,918	97,360
Stock price appreciation milestones	1,184	1,346
Stockholders' equity	396,982	368,417
Total liabilities and stockholders' equity	$ 528,817	$ 506,217

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