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): May 09, 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 May 9, 2024, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 9, 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: May 9, 2024

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

Exhibit 99.1

Fate Therapeutics Reports First Quarter 2024 Financial Results and Business Updates

First Lupus Patient Treated with FT819 CAR T-cell Product Candidate in Phase 1 Autoimmunity Study; Future Clinical Development of FT819 to Focus Exclusively on Autoimmune Disease

Enrollment Initiated with FT522 CAR NK Cell Product Candidate in Conditioning-free Treatment Arm of Phase 1 B Cell Lymphoma Study

First Patient Treated with FT825 / ONO-8250 CAR T-cell Product Candidate in Phase 1 Solid Tumor Study

$391 Million in Cash, Cash Equivalents, and Investments

San Diego, CA – May 9, 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 first quarter ended March 31, 2024.

"We made great progress across three key areas of clinical focus – we treated the first patient with our off-the-shelf FT819 CAR T-cell therapy for autoimmunity, we initiated patient enrollment without conditioning chemotherapy for our ADR-armed FT522 CAR NK cell therapy, and we treated the first patient with our multiplexed-engineered FT825 CAR T-cell therapy for solid tumors," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "As we look toward the middle of the year, we plan to expand clinical development in autoimmunity with our off-the-shelf FT819 and FT522 programs, where we believe our iPSC product platform is highly differentiated and has the potential to overcome numerous challenges that hinder treatment of patients with cell therapies, such as the requirement for apheresis and Cy / Flu conditioning, extended hospitalization, risk of secondary malignancies, and limited access. In addition, while we continue with the preclinical assessment of our next-generation, BCMA-targeted cell product candidates, we do not intend to further advance FT576 into Phase 1 dose expansion in relapsed / refractory multiple myeloma."

FT819 iPSC-derived CAR T-cell Program

- **First SLE Patient Treated in 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 novel CD19-targeted 1XX chimeric antigen receptor (CAR) construct into the T-cell receptor alpha constant (TRAC) locus (NCT06308978). The first patient, a 27 year-old woman diagnosed with SLE 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 was discharged after a three-day hospital stay without any notable adverse events. In a "first-of-kind" translational assessment using a sample of the patient's blood obtained prior to administration of conditioning chemotherapy,

FT819 induced rapid and potent depletion of the patient's CD19+ B cells in an *ex vivo* cytotoxicity assay.

- **Phase 1 BCM Study Data Establish Proof-of-Concept for Autoimmune Disease.** At the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting, the Company today presented preclinical and translational data from its FT819 Phase 1 study in relapsed / refractory B cell malignancies (BCM), which showed that a single dose of FT819 exhibits multiple mechanisms implicated in generating an immune reset in patients with B cell-mediated autoimmune diseases. Clinical observations included: dose-dependent pharmacokinetics, reaching Cmax at Day 8 with persistence through the first two weeks in the periphery; rapid, deep, and sustained CD19+ B cell depletion in the peripheral blood using standard Cy / Flu and alternative conditioning chemotherapy regimens; patient case studies of secondary and tertiary tissue trafficking, infiltration, and activity with CD19+ B cell elimination in tissue; and patient case studies of plasma cell depletion and B cell reconstitution, which showed recovery of naïve B cells with little to no recovery of activated memory B cells or plasmablasts.
- **Dose-escalation Completed in Phase 1 BCM Study with Further Clinical Development to Focus Exclusively on Autoimmunity.** The Company has successfully completed dose escalation in its Phase 1 BCM study, demonstrating safety and tolerability of FT819 at a single dose up to 1.08 billion cells (NCT04629729), and intends to pursue further clinical development exclusively in autoimmunity. 43 heavily pre-treated patients (B cell lymphoma, n=25; chronic lymphocytic leukemia, n=12; and acute lymphocytic leukemia, n=6) 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 immune effector-cell associated neurotoxicity syndrome (ICANS) or graft-versus-host disease (GvHD), and low incidence (14%) of only low-grade cytokine release syndrome (CRS). There were no study discontinuations or deaths related to FT819. Clinical responses were observed across all three histologies. In 17 patients with aggressive large B cell lymphoma, 12 (71%) of whom had previously received autologous CD19-targeted CAR T-cell therapy, the overall response and complete response rates were 47% and 24%, respectively.

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

- **First Patient Treated 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). The first patient was diagnosed with HER2-positive gastroesophageal junction (GEJ) adenocarcinoma, had progressed after receiving multiple lines of treatment including HER2-targeted therapies, and was administered standard conditioning chemotherapy followed by a single dose of FT825 / ONO-8250 as monotherapy at 100 million cells. 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.

FT522 iPSC-derived CAR NK Cell Program

- **Conditioning-free Treatment Arm of Phase 1 BCL Study Open for Enrollment.** 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), patient enrollment has now been initiated in the first three-dose cohort at 300 million cells per dose without conditioning chemotherapy (Regimen B). Three patients have been treated with conditioning chemotherapy in the first three-dose cohort at 300 million cells per dose (Regimen A). There were no dose-limiting toxicities and no events of any grade of CRS, ICANS, or GvHD, and dose escalation is ongoing at 900 million cells per dose.

- **ASGCT Presentation Data Show ADR Differentiation and Proof-of-Concept for Autoimmunity.** At the ASGCT conference, the Company today presented preclinical data as well as early translational data from its ongoing Phase 1 BCL study. In a novel re-challenge assay using peripheral blood mononuclear cells (PBMCs) from unmatched SLE donors, 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 in Regimen A, 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. The Company intends to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in the middle of 2024 for the treatment of various autoimmune diseases with FT522, including without administration of conditioning chemotherapy to patients.

FT576 iPSC-derived CAR NK Cell Program

- **Dose Escalation Completed in Phase 1 Multiple Myeloma Study.** The Company has completed dose escalation in its multi-center, Phase 1 clinical trial of FT576, its BCMA-targeted CAR NK cell product candidate, for relapsed / refractory multiple myeloma (NCT05182073). Using a standard conditioning chemotherapy regimen, 12 patients were treated with a three-dose treatment schedule at 1 billion cells per dose (n=6) or at 2.5 billion cells per dose (n=6) as monotherapy or in combination with CD38-targeted monoclonal antibody therapy. There were no dose-limiting toxicities and no events of any grade of CRS, ICANS or GvHD. Response assessment is ongoing at 2.5 billion cells per dose. Five of six (83%) heavily pre-treated patients achieved a clinical response at 1 billion cells per dose, including two penta-exposed patients treated with FT576 as monotherapy that achieved very good partial responses. The Company is continuing to assess the FT576 Phase 1 dose-escalation dataset and to preclinically evaluate the potential of its next-generation, BCMA-targeted cell product candidates, including for the treatment of multiple myeloma and autoimmune diseases, and does not intend to further advance FT576 into Phase 1 dose expansion in relapsed / refractory multiple myeloma.

First Quarter 2024 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of March 31, 2024 were $391.1 million, which includes net proceeds from the closing of the Company's approximately $80 million underwritten offering of common stock at $5.50 per share and approximately $20 million concurrent private placement of pre-funded warrants at $5.499 per pre-funded warrant in the first quarter of 2024.
- **Total Revenue:** Revenue was $1.9 million for the first quarter of 2024, which was derived from the Company's 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 first quarter of 2024, GAAP operating expenses were $53.0 million, including research and development expenses of $32.1 million and general and administrative expenses of $20.9 million. Such amounts included $11.0 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 March 31, 2024. Each preferred share is convertible into five common shares.

Today's Conference Call and Webcast
The Company will conduct a conference call today, Thursday, May 9, 2024 at 5:00 p.m. ET to review financial and operating results for the quarter and full year ended March 31, 2024. In order to participate in the conference call, please dial (833) 630-1956 (domestic) and (412) 317-1837 (international). The live webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

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 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 March 31,	
	2024	**2023**
Collaboration revenue	$ 1,925	$ 58,980
Operating expenses:		
Research and development	32,138	65,629
General and administrative	20,855	21,943
Total operating expenses	52,993	87,572
Loss from operations	(51,068)	(28,592)
Other income (expense):		
Interest income	4,149	3,694
Change in fair value of stock price appreciation milestones	(1,394)	1,718
Other Income	309	4,299
Total other income (expense), net	3,064	9,711
Net loss	$ (48,004)	$ (18,881)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities, net	(209)	1,208
Comprehensive loss	$ (48,213)	$ (17,673)
Net loss per common share, basic and diluted	$ (0.47)	$ (0.19)
Weighted–average common shares used to compute basic and diluted net loss per share	101,104,345	98,054,687

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 121,322	$ 41,870
Accounts receivable	858	1,826
Short-term investments	262,222	273,305
Prepaid expenses and other current assets	9,973	14,539
Total current assets	394,375	331,540
Long-term investments	7,595	980
Operating lease right-of-use asset	60,620	61,675
Other long-term assets	107,302	112,022
Total assets	$ 569,892	$ 506,217
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 38,808	$ 32,233
Deferred revenue, current portion	159	685
Operating lease liability, current portion	6,402	6,176
Total current liabilities	45,369	39,094
Operating lease liability, net of current portion	95,668	97,360
Stock price appreciation milestones, net of current portion	2,740	1,346
Stockholders' equity	426,115	368,417
Total liabilities and stockholders' equity	$ 569,892	$ 506,217

Contact:
Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina.tartaglia@sternir.com