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 03, 2023

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** **(Address of Principal Executive Offices)**	**92131** **(Zip Code)**

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

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $.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 3, 2023, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 3, 2023
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 3, 2023

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

Fate Therapeutics Reports First Quarter 2023 Financial Results and Business Updates

Dose Escalation Ongoing in Landmark Phase 1 Study of FT819 CD19-targeted 1XX CAR T-cell Program; Interim Clinical Data Demonstrated Favorable Safety Profile and Complete Responses in Aggressive Large B-cell Lymphoma

FT576 BCMA-targeted CAR NK Cell Program Accruing Patients in Multi-dose Escalation Cohorts for Multiple Myeloma; Initial Translational Data Support Potential of Combination Regimen to Induce Differentiated Immune Reconstitution Profile and Extend FT576 Functional Persistence

Clinical Initiation of FT522 ADR-armed, CD19-targeted CAR NK Cell Program for B-cell Lymphoma Anticipated in 2H23; Preclinical Studies Ongoing to Extend Clinical Reach to Autoimmune Diseases

Completed Corporate Restructuring and Strategic Assessment of Pipeline Assets; Ended 1Q23 with $426 Million in Cash, Cash Equivalents, and Receivables Supporting Runway into 2H25

San Diego, CA –May 3, 2023 – 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 disorders, today reported business highlights and financial results for the first quarter ended March 31, 2023.

“Over the first months of 2023, we have sharpened our clinical focus and significantly reduced our operating expenses, creating the necessary cash runway to achieve key milestones across our multiplexed-engineered CAR NK and CAR T-cell pipeline. We sincerely thank our employees whose patience and perseverance have allowed us to emerge through this transition period with a renewed sense of energy, commitment, and drive to bring first-in-class, iPSC-derived cellular immunotherapies to patients with cancer and autoimmune disorders,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We are now well-positioned to clinically assess higher therapeutic exposures for our FT576 BCMA-targeted CAR NK cell program in multiple myeloma and our FT819 CD19-targeted CAR T-cell program in B-cell malignancies. In addition, we aim to bring our FT522 CD19-targeted CAR NK cell program, which incorporates our proprietary ADR technology designed to enhance NK cell potency, extend functional persistence, and resist host immune cell rejection, into clinical development in the second half of 2023 for B-cell lymphoma, and intend to expand its clinical reach to include severe autoimmune disorders. Finally, we are excited to be jointly developing our clinical strategy with ONO Pharmaceutical for FT825/ONO-8250, our HER2-targeted CAR T-cell collaboration program for solid tumors for which we plan to submit an IND application in the second half of 2023.”

NK Cell Programs

- **FT576 BCMA-targeted CAR NK Cell Program Accruing Patients in Multi-dose Escalation Cohorts for Multiple Myeloma.** The Company’s Phase 1 study of FT576, its multiplexed-engineered, BCMA-targeted chimeric antigen receptor (CAR) NK cell product candidate for relapsed / refractory multiple

myeloma, is currently enrolling two-dose treatment cohorts as monotherapy and in combination with CD38-targeted monoclonal antibody (mAb) therapy at 300 million cells per dose. Upon clearance of the current treatment cohorts, the Company plans to open and assess three-dose treatment cohorts starting at 1 billion cells per dose. At the 2022 American Society of Hematology (ASH) Annual Meeting in December, the Company presented interim Phase 1 clinical data from nine heavily pre-treated patients in the single-dose cohorts, which showed encouraging clinical evidence of BCMA-targeted activity and a favorable safety profile indicating the potential for administration in the outpatient setting. Translational data from the CD38-targeted mAb combination regimen showed rapid and selective depletion of CD38-positive patient immune cells in the peripheral blood and bone marrow that extended through the first month of therapy, indicating that the regimen may uniquely serve to attenuate reconstitution of activated T cells, extend functional persistence of FT576, and enable dual-antigen targeting of myeloma cells.

- **Initiation of Clinical Assessment of FT522 ADR-armed, CD19-targeted CAR NK Cell Program Anticipated in 2H23.** FT522 is the Company's first product candidate to incorporate its proprietary alloimmune defense receptor (ADR) technology, which has been shown in preclinical studies to increase NK cell potency, enhance functional persistence, and confer resistance to host immune cell allo-reactivity. The Company has recently submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to investigate the safety and activity of FT522 in combination with CD20-targeted mAb therapy in patients with B-cell lymphoma, including without prior administration of intensive conditioning chemotherapy. In addition, the Company is currently conducting preclinical studies to support clinical assessment of FT522 in autoimmune disease, including in combination with CD20- and CD38-targeted mAb therapy, to selectively target and durably deplete pathogenic B cells, plasma cells, and auto-reactive T cells.

T-cell Programs

- **First-of-kind FT819 Program Advancing in Single-dose Escalation Cohorts for B-cell Malignancies.** The Company's landmark Phase 1 clinical trial of FT819, which is the first-ever clinical investigation of a T-cell product candidate manufactured from a clonal master iPSC line, is currently enrolling patients in single-dose escalation cohorts at 540 million cells in B-cell lymphoma and at 180 million cells in chronic lymphocytic leukemia. At the 2022 ASH Annual Meeting, the Company presented interim Phase 1 clinical data from eight patients with relapsed / refractory aggressive large B-cell lymphoma treated with a single dose of FT819 ranging from 90 million cells to 360 million cells, which demonstrated a favorable safety profile and objective responses including in patients who were not eligible for or had previously failed autologous CD19-targeted CAR T-cell therapy. FT819 incorporates several novel features including the integration of a novel CD19-targeted 1XX CAR construct into the T-cell receptor alpha constant (TRAC) locus, which is intended to promote uniform CAR expression, enhance T-cell potency, and prevent graft-versus-host disease.
- **2023 IND Submission Planned for HER2-targeted CAR T-cell Program for Solid Tumors.** Under the Company's collaboration with ONO Pharmaceutical Co., Ltd. (ONO), the companies are co-developing FT825/ONO-8250, an iPSC-derived CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors. IND-enabling activities for FT825/ONO-8250 are currently ongoing, and the Company plans to submit an IND application to the FDA in 2023 to jointly conduct with ONO a Phase 1 study for the treatment of patients with HER2-positive solid tumors. The

multiplexed-engineered, iPSC-derived CAR T-cell product candidate incorporates seven novel synthetic controls designed to enhance effector cell function and overcome unique challenges in treating solid tumors, including a novel HER2-targeted binding domain with a differentiated targeting profile, a synthetic CXCR2 receptor to promote cell trafficking, a synthetic TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment, and a synthetic interleukin-7 receptor fusion protein to induce T-cell activation.

Strategic Pipeline Prioritization & Corporate Restructuring

During the first quarter of 2023, in connection with the termination of its collaboration with Janssen Biotech, Inc. (Janssen), the Company discontinued all collaboration activities, including withdrawing an IND application previously allowed by the FDA for a first collaboration product for the treatment of B-cell lymphoma. In addition, following a strategic review of its wholly-owned iPSC-derived NK cell and T-cell programs, the Company focused its operations on advancing its most innovative and differentiated programs and initiated the discontinuation of its FT516, FT596, FT538, and FT536 NK cell product candidates. As part of its corporate restructuring, the Company reduced its workforce to approximately 220 employees.

First Quarter 2023 Financial Results & 2023 Guidance

- **Cash & Investment Position:** Cash, cash equivalents and investments as of March 31, 2023 were $412.8 million. In addition, as of March 31, 2023, cash receivables from collaborations were $13.5 million. The Company expects its cash, cash equivalents, and investments to exceed $300 million at year-end 2023.
- **Total Revenue:** Revenue was $59.0 million for the first quarter of 2023, of which $52.3 million was associated with the termination of its collaboration with Janssen and $6.7 million was derived from its ongoing collaboration with ONO. Under the ONO collaboration, a one-time amount of $6.2 million was recorded as revenue for the first quarter of 2023 associated with the Company's conduct of IND-enabling activities for FT825/ONO-8250, for which ONO exercised its development and commercialization option in November 2022. For each of the remaining three quarters of 2023, the Company expects to recognize approximately $0.8 million in revenue under the ONO collaboration in connection with its conduct of preclinical development activities for a second collaboration candidate targeting an undisclosed solid tumor antigen.
- **Total Operating Expenses:** For the first quarter of 2023, GAAP operating expenses were $87.6 million, including research and development expenses of $65.6 million and general and administrative expenses of $21.9 million. Such amounts included $11.0 million of non-cash stock-based compensation expense and a one-time charge of $12.9 million for severance and other employee termination-related costs associated with the Company's corporate restructuring. For the full year ending December 31, 2023, the Company expects its GAAP operating expenses to be between $265 million to $285 million.
- **Shares Outstanding:** Common shares outstanding were 98.2 million, and preferred shares outstanding were 2.8 million, as of March 31, 2023. Each preferred share is convertible into five common shares.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Wednesday, May 3, 2023 at 5:00 p.m. ET to review financial and operating results for the quarter ended March 31, 2023. In order to participate in the conference call,

please register using the conference link here**.** 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
The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, multiplexed-engineered cell products that are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple mechanisms of therapeutic importance to patients. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's platform combines multiplexed engineering and single-cell selection of human iPSCs 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 renewable cell source to manufacture multiplexed-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 400 issued patents and 450 pending patent applications.

About FT576
FT576 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with four functional components: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that targets B-cell maturation antigen (BCMA); a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; an IL-15 receptor fusion (IL-15RF) that augments NK cell activity; and the deletion of the CD38 gene (CD38KO), which promotes persistence and function in high oxidative stress environments. In preclinical studies, FT576 has demonstrated that the high-avidity binding of the BCMA-targeted CAR construct enables sustained tumor control against various multiple myeloma cell lines, including in long-term *in vivo* xenograft mouse models. Additionally, in combination with daratumumab, FT576 has shown complete tumor clearance and improved survival compared to primary BCMA-targeted CAR T cells in a disseminated xenograft model of multiple myeloma. FT576 is being investigated in a multicenter Phase 1 clinical trial for the treatment of relapsed / refractory multiple myeloma as a monotherapy and in combination with daratumumab (NCT05182073).

About FT819
FT819 is an investigational, universal, off-the-shelf, T-cell receptor (TCR)-less CD19 chimeric antigen receptor (CAR) T-cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line, which is engineered with the following features designed to improve the safety and efficacy of CAR19 T-cell therapy: a novel 1XX CAR signaling domain, which has been shown to extend T-cell effector function without eliciting exhaustion; integration of the CAR19 transgene directly into the T-cell receptor alpha constant (TRAC) locus, which has been shown to promote uniform CAR19 expression and enhanced T-cell potency; and complete bi-allelic disruption of TCR expression for the prevention of graft-versus-host disease. FT819

demonstrated antigen-specific cytolytic activity *in vitro* against CD19-expressing leukemia and lymphoma cell lines comparable to that of primary CAR T cells, and persisted and maintained tumor clearance in the bone marrow in an *in vivo* disseminated xenograft model of lymphoblastic leukemia. FT819 is being investigated in a multicenter Phase 1 clinical trial for the treatment of relapsed / refractory B-cell malignancies, including B-cell lymphoma, chronic lymphocytic leukemia, and acute lymphoblastic leukemia (NCT04629729).

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 disorders. Using its proprietary iPSC product platform, the Company has established a leadership position in creating multiplexed-engineered iPSC lines and in the manufacture and clinical development of off-the-shelf, iPSC-derived cell products. The Company's effector cell pipeline includes multiplexed-engineered, iPSC-derived natural killer (NK) cell and T-cell product candidates, which incorporate novel synthetic controls of cell function, such as chimeric antigen receptors (CARs) to target tumor-associated antigens, and are intended to deliver multiple mechanisms of therapeutic importance to patients including in combination with well-established cancer therapies. 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 progress of and plans related to the Company's product candidates, clinical studies and preclinical research and development programs, the therapeutic and market potential of the Company's product candidates, the Company's clinical and product development strategy, the Company's plans to submit IND applications for its FT522 CD19-targeted CAR NK cell program and its FT825/ONO-8250 HER2-targeted CAR T-cell solid tumor program under its collaboration with ONO, the Company's expectations regarding its receipt of future payments for milestones achieved under its collaboration agreement with Janssen prior to the termination of the agreement, the anticipated effects of the Company's workforce reduction and reprioritization of preclinical and clinical development activities, including its projected cash runway, and the timing of such events. 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 product candidates may not demonstrate the requisite safety or efficacy 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, and any adverse events or other negative results that may be observed during preclinical or clinical development), the risk that results observed in preclinical studies of its product candidates may not be replicated in ongoing or future clinical trials, 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 Pharmaceutical, Ltd. or other parties with which the Company may enter into future collaborations on the agreed upon terms, the risk that research funding and milestone payments received by the Company under its collaborations 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,	
	2023	**2022**
Collaboration revenue	$ 58,980	$ 18,414
Operating expenses:		
Research and development	65,629	72,139
General and administrative	21,943	20,742
Total operating expenses	87,572	92,881
Loss from operations	(28,592)	(74,467)
Other income (expense):		
Interest income	3,694	418
Change in fair value of stock price appreciation milestones	1,718	8,359
Other Income	4,299	—
Total other income (expense), net	9,711	8,777
Net loss	$ (18,881)	$ (65,690)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities, net	1,208	(2,088)
Comprehensive loss	$ (17,673)	$ (67,778)
Net loss per common share, basic and diluted	$ (0.19)	$ (0.68)
Weighted–average common shares used to compute basic and diluted net loss per share	98,054,687	96,343,529

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 42,020	$ 61,333
Accounts receivable	13,500	38,480
Short-term investments	366,878	374,894
Prepaid expenses and other current assets	15,490	27,367
Total current assets	437,888	502,074
Long-term investments	3,912	4,942
Operating lease right-of-use asset	64,682	66,069
Other long-term assets	123,854	132,476
Total assets	$ 630,336	$ 705,561
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 41,368	$ 62,197
Deferred revenue, current portion	1,738	42,226
CIRM award liability, current portion	—	4,000
Operating lease liability, current portion	5,545	5,628
Total current liabilities	48,651	114,051
Operating lease liability, net of current portion	102,070	103,710
Stock price appreciation milestones, net of current portion	2,143	3,861
Stockholders' equity	477,472	483,939
Total liabilities and stockholders' equity	$ 630,336	$ 705,561

Contact:
Matthew Guido
Stern Investor Relations, Inc.
212.362.1200
matthew.guido@sternir.com