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): February 28, 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 February 28, 2023, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2022. 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 February 28, 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: February 28, 2023

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

Fate Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Updates

Ended 2022 with Approximately $475 Million in Cash, Cash Equivalents, and Receivables

Multi-dose Treatment Cohorts Initiated in FT576 Phase 1 Study for Multiple Myeloma; Interim Clinical Data from Single-dose Cohorts Showed Objective Responses and Selective Depletion of Activated Host Immune Cells

Mid-2023 IND Submission Planned for FT522 NK Cell Program in B-cell Lymphoma; Intent to Expand Clinical Investigation to include Severe Autoimmune Disorders

FT819 Phase 1 Study of First-ever iPSC-derived CAR T-cell Therapy Ongoing; Interim Clinical Data Showed Favorable Safety Profile and Complete Responses in Large B-cell Lymphoma

IND Submission for FT825/ONO-8250 CAR T-cell Product Candidate for Solid Tumors Planned for 2023 under Ono Collaboration

San Diego, CA – February 28, 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 fourth quarter and full year ended December 31, 2022.

“We have focused our operations on advancing our most innovative and differentiated programs for patients with cancer and autoimmune disorders, and we have substantially reduced our expenses with the intent of providing the necessary cash runway to achieve key clinical milestones across our multiplexed-engineered, iPSC-derived CAR NK and CAR T-cell product candidates,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We are now enrolling multi-dose treatment cohorts with FT576 for multiple myeloma, including in combination with CD38-targeted monoclonal antibody therapy to promote dual-antigen targeting and selective depletion of activated host immune cells. We also plan to submit an IND application in the middle of 2023 for FT522, which incorporates our proprietary ADR technology designed to enable patient dosing with reduced conditioning chemotherapy, and intend to initiate clinical development in B-cell lymphoma with plans to expand clinical investigation to severe autoimmune disorders. In addition, we are excited with the progress of our iPSC-derived CAR T-cell pipeline for the treatment of hematologic malignancies and solid tumors. Dose escalation is continuing in our landmark Phase 1 study of FT819, with interim clinical data showing a favorable safety profile and demonstrating complete responses in heavily pre-treated patients with aggressive B-cell lymphoma. Finally, we plan to submit an IND application in 2023 for FT825/ONO-8250 under our collaboration with ONO Pharmaceutical, which incorporates seven novel synthetic controls designed to more effectively attack solid tumors.”

NK Cell Programs

- **Multi-dose Treatment Cohorts Enrolling in FT576 Phase 1 Study for Multiple Myeloma.** At the 2022 American Society of Hematology (ASH) Annual Meeting in December, the Company presented interim Phase 1 clinical data from the first nine patients treated with a single dose of FT576, its multiplexed-engineered, BCMA-targeted chimeric antigen receptor (CAR) NK cell product candidate for relapsed / refractory multiple myeloma. Clinical data from the single-dose treatment cohorts in heavily pre-treated patients (median of 5 prior lines of therapy; range 3-10) showed encouraging clinical evidence of BCMA-targeted activity and a favorable safety profile indicating the potential for administration in the outpatient setting. Of the six patients treated with a single dose of FT576 as monotherapy (n=3 at 100 million cells; n=3 at 300 million cells), one patient treated at 300 million cells who was triple-refractory and had received five prior lines of therapy achieved a very good partial response (VGPR). In addition, three patients were treated with a single dose of FT576 at 100 million cells in combination with CD38-targeted monoclonal antibody (mAb) therapy to promote dual-antigen targeting of plasma cells, with one patient achieving a partial response (PR). Notably, translational data from the single-dose combination cohort showed rapid and selective depletion of CD38-positive patient immune cells through the first month of therapy, suggesting that CD38-targeted mAb therapy may also serve as a conditioning agent to potentially mitigate the risk of rejection of FT576. The Company is currently enrolling two-dose treatment cohorts as monotherapy and in combination with CD38-targeted mAb therapy at 300 million cells per dose and, upon clearance, the Company plans to open and assess three-dose treatment cohorts starting at 1 billion cells per dose.
- **IND Submission Planned in Mid-2023 for FT522 CD19-targeted CAR NK Cell Program.** The Company has leveraged its unique ability to create multiplexed-engineered iPSC lines in its development of FT522, a next-generation CD19-targeted CAR NK cell program incorporating five novel synthetic controls of cell function designed to increase NK cell potency, enhance functional persistence, and reduce or eliminate the need to administer conditioning chemotherapy to patients. FT522 is the first product candidate to incorporate the Company's proprietary alloimmune defense receptor (ADR) technology for which the Company presented preclinical data at the 2022 ASH Annual Meeting in December demonstrating that ADR-armed, iPSC-derived CAR NK cells have the potential to proliferate, functionally persist, and durably kill tumor cells while resisting rejection by allo-reactive immune cells. Overall, the novel synthetic controls integrated into FT522 have the potential to significantly improve safety and clinical benefit, facilitate ease of combination with standard-of-care regimens including CD20- and CD38-targeted mAb therapy, and enable use in the treatment of B-cell lymphoma, multiple myeloma, and severe autoimmune disorders. The Company intends to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in mid-2023 to commence a Phase 1 study of FT522 in combination with CD20-targeted mAb therapy for the treatment of B-cell lymphoma, including without administration of intensive conditioning chemotherapy to patients.

T-cell Programs

- **Dose Escalation Continuing in FT819 Phase 1 Study for B-cell Malignancies.** The landmark clinical trial is the first-ever clinical investigation of a T-cell product candidate manufactured from a clonal master iPSC line. FT819 incorporates several first-of-kind 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. At

the 2022 ASH Annual Meeting, the Company presented interim clinical data from its ongoing Phase 1 study of FT819, which showed a favorable safety profile and demonstrated objective responses in heavily pre-treated patients, including in patients who were not eligible for or had previously failed autologous CD19-targeted CAR T-cell therapy. Of the eight patients with aggressive large B-cell lymphoma (median of 4.5 prior lines of therapy; range 3-7) treated with a single dose of FT819 ranging from 90 million cells to 360 million cells: two patients were naïve to CAR T-cell therapy, one of whom achieved a complete response (CR); and six patients were previously treated with CAR T-cell therapy, two of whom achieved an objective response including a CR in a patient with diffuse large B-cell lymphoma previously treated with seven prior lines of therapy and who did not respond to autologous CD19-targeted CAR T-cell therapy. Dose escalation is currently ongoing in single-dose treatment regimens at 540 million cells in B-cell lymphoma and at 180 million cells in chronic lymphocytic leukemia.

- **2023 IND Submission Planned for FT825/ONO-8250 HER2-targeted CAR T-cell Solid Tumor Program.** At the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting held in November 2022, the Company presented preclinical data of FT825/ONO-8250, a multiplexed-engineered, iPSC-derived CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors that the Company is co-developing under its collaboration with ONO Pharmaceutical Co., Ltd. (ONO). The product candidate incorporates seven novel synthetic controls designed to enhance effector cell function and overcome unique challenges in treating solid tumors with cell-based cancer immunotherapies, including cell trafficking, tumor infiltration, and immune cell suppression in the tumor microenvironment. Preclinical data of FT825/ONO-8250 presented at SITC highlighted the differentiated targeting profile of its novel HER2-targeted binding domain as well as the potential of its synthetic CXCR2 receptor to promote cell trafficking, its synthetic TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment, and its synthetic interleukin-7 receptor fusion protein to induce T-cell activation. The parties are conducting IND-enabling activities for FT825/ONO-8250, and expect to submit an IND application to the FDA in 2023 to commence a Phase 1 study for the treatment of patients with HER2-positive solid tumors.

Corporate Developments

- **Termination of Janssen Collaboration.** On January 3, 2023, the Company received notice of termination from Janssen Biotech, Inc. (“Janssen”) of the Collaboration and Option Agreement dated April 2, 2020 by and between the Company and Janssen, pursuant to which Janssen and the Company had agreed to collaborate to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer, which will take effect April 3, 2023. During the fourth quarter of 2022, Janssen exercised its second commercial option for a collaboration product under the agreement, for which the Company expects to receive a $10 million milestone payment. In addition, during the fourth quarter of 2022, Janssen authorized the submission of, and the FDA allowed, an IND application for a first collaboration product for the treatment of B-cell lymphoma, for which the Company expects to receive a $3 million milestone payment. As a result of the collaboration’s termination, during the first quarter of 2023, the Company and Janssen are winding down all collaboration activities, including discontinuing development of all collaboration products, at the expense of Janssen.
- **Pipeline Prioritization and Restructuring.** On January 5, 2023, the Company completed a strategic review of its NK cell programs and elected to advance its most innovative and differentiated product

candidates. As a result of this program prioritization as well as the termination of the Janssen collaboration, the Company is discontinuing development of its FT516, FT596, FT538, and FT536 NK cell programs and is reducing its workforce in the first quarter of 2023 to approximately 220 employees. The Company expects to incur charges of approximately $12 million to $16 million for severance and other employee termination-related costs in the first quarter of 2023.

Fourth Quarter 2022 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of December 31, 2022 were $441.2 million. In addition, as of December 31, 2022, cash receivables from the Company's collaborations with Janssen and ONO were $38.5 million, which includes $22.5 million from the exercise of certain options and $3.0 million from the achievement of a regulatory milestone during the fourth quarter of 2022.
- **Total Revenue:** Revenue was $44.4 million for the fourth quarter of 2022, which was derived from the Company's collaborations with Janssen and ONO. During the fourth quarter, the Company recognized one-time revenue of: $12.5 million in connection with the Company and ONO each exercising their respective options for development and commercialization of FT825/ONO-8250; and $13.0 million in connection with the exercise of an option by Janssen and the achievement of a regulatory milestone under the Janssen collaboration.
- **R&D Expenses:** Research and development expenses were $87.2 million for the fourth quarter of 2022, which includes $12.4 million of non-cash stock-based compensation expense.
- **G&A Expenses:** General and administrative expenses were $21.6 million for the fourth quarter of 2022, which includes $7.0 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 97.3 million, and preferred shares outstanding were 2.8 million, as of December 31, 2022. Each preferred share is convertible into five common shares.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Tuesday, February 28, 2023 at 5:00 p.m. ET to review financial and operating results for the quarter and full year ended December 31, 2022. 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Collaboration revenue	$ 44,356	$ 17,067	$ 96,300	$ 55,846
Operating expenses:				
Research and development	87,191	69,514	320,454	215,519
General and administrative	21,584	16,935	84,232	57,321
Total operating expenses	108,775	86,449	404,686	272,840
Loss from operations	(64,419)	(69,382)	(308,386)	(216,994)
Other income (expense):				
Interest income	2,880	297	5,842	1,309
Change in fair value of stock price appreciation milestones	5,176	464	20,307	3,534
Other Income	—	—	516	—
Total other income (expense), net	8,056	761	26,665	4,843
Net loss	$ (56,363)	$ (68,621)	$ (281,721)	$ (212,151)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities, net	1,399	(689)	(1,092)	(832)
Comprehensive loss	$ (54,964)	$ (69,310)	$ (282,813)	$ (212,983)
Net loss per common share, basic and diluted	$ (0.58)	$ (0.72)	$ (2.91)	$ (2.24)
Weighted–average common shares used to compute basic and diluted net loss per share	97,220,972	95,788,351	96,826,058	94,747,311

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 61,333	$ 133,583
Accounts receivable	38,480	8,676
Short-term investments	374,894	482,327
Prepaid expenses and other current assets	27,367	8,826
Total current assets	502,074	633,412
Long-term investments	4,942	100,664
Operating lease right-of-use asset	66,069	70,720
Other long-term assets	132,476	116,659
Total assets	$ 705,561	$ 921,455
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 62,197	$ 51,024
Deferred revenue, current portion	42,226	21,483
CIRM award liability, current portion	4,000	3,200
Operating lease liability, current portion	5,628	5,577
Total current liabilities	114,051	81,284
Deferred revenue, net of current portion	—	27,124
CIRM award liability, net of current portion	—	800
Operating lease liability, net of current portion	103,710	109,241
Stock price appreciation milestones, net of current portion	3,861	24,168
Stockholders' equity	483,939	678,838
Total liabilities and stockholders' equity	$ 705,561	$ 921,455

Contact:
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