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 26, 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 February 26, 2024, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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 February 26, 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: February 26, 2024

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

Exhibit 99.1

Fate Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Business Updates

CIRM Grant Awarded to Support Phase 1 Autoimmunity Study of FT819 CD19-targeted CAR T-cell Program for Systemic Lupus Erythematosus; Study Start-up Ongoing at Multiple Clinical Sites

First Patient Treated in Phase 1 Study of FT522 ADR-armed, CD19-targeted CAR NK Cell Program; Dose Escalation Designed to Assess 3-dose Treatment Schedule with and without Chemotherapy Conditioning

Phase 1 Study Initiated of FT825 / ONO-8250 CAR T-cell Program for Solid Tumors; Incorporates Seven Synthetic Controls including Novel Cancer-specific CAR Targeting HER2

$316 Million in Cash, Cash Equivalents, and Investments

San Diego, CA – February 26, 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 disorders, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2023.

"We have started the year with strong momentum across our iPSC product platform in oncology and autoimmunity, including the award of a grant by the California Institute of Regenerative Medicine to support Phase 1 clinical investigation of our off-the-shelf FT819 CAR T-cell program in systemic lupus erythematosus," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We have also treated the first patient with FT522, our off-the-shelf CAR NK cell program targeting CD19+ B cells, which is our first product candidate to incorporate our proprietary Alloimmune Defense Receptor technology that is designed to reduce or eliminate the need for administration of intense chemotherapy conditioning to patients. In addition, we have initiated the Phase 1 study of our FT825 / ONO-8250 CAR T-cell program in solid tumors, which incorporates seven synthetic controls of cell function including a novel cancer-specific binding domain targeting HER2. We are well positioned to generate initial clinical data across these off-the-shelf programs during 2024."

FT819 iPSC-derived CAR T-cell Program

- **CLIN2 Grant Awarded by CIRM to Fund FT819 Phase 1 Autoimmunity Study in SLE.** In February, the Company was awarded $7.9 million by the California Institute for Regenerative Medicine (CIRM) to support clinical investigation of FT819 in patients with systemic lupus erythematosus (SLE). FT819 is the Company's off-the-shelf CAR T-cell product candidate that incorporates several novel synthetic controls of cell function, including the integration of a novel CD19-targeted 1XX chimeric antigen receptor (CAR) construct into the T-cell receptor alpha constant (TRAC) locus that is intended to promote uniform CAR expression, enhance T-cell potency, and prevent

graft-versus-host disease (GvHD). The multi-center, Phase 1 clinical trial for SLE is designed to evaluate the safety, pharmacokinetics, and anti-B-cell activity of a single dose of FT819 administered following a standard three-day chemotherapy conditioning regimen. The Company is currently conducting study start-up activities at multiple U.S. clinical sites.

- **Dose Escalation Ongoing in Phase 1 Study for B-cell Lymphoma.** The Company's landmark clinical trial of FT819 for the treatment of relapsed / refractory B-cell malignancies is the first-ever clinical investigation of a T-cell product candidate manufactured from a clonal master iPSC line. The Company is currently enrolling patients in single-dose treatment cohorts at 540 million cells and at 1.08 billion cells using a standard three-day chemotherapy conditioning regimen. Any further clinical development of FT819 for the treatment of B-cell malignancies will be determined by the Company based on safety and activity at these higher dose levels. Clinical data previously presented by the Company from the first 11 patients with relapsed / refractory B-cell lymphoma treated with a single dose of FT819 at up to 360 million cells showed anti-tumor activity including three complete responses and one partial response, CAR T-cell expansion that peaked in the peripheral blood between Days 8 and 11, and a favorable safety profile with no dose-limiting toxicities, no events of any grade of immune effector-cell associated neurotoxicity syndrome (ICANS) or GvHD, and no events of Grade 3 or greater cytokine release syndrome (CRS).

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

- **Phase 1 Study Initiated with HER2-targeted CAR T-cell for Advanced Solid Tumors.** In January, the Company initiated enrollment of a multi-center, Phase 1 clinical trial of FT825 / ONO-8250 under its collaboration with Ono Pharmaceutical Co., Ltd. (Ono). 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 targeting human epidermal growth factor receptor 2 (HER2). Preclinical data of FT825 / ONO-8250 presented at the 2023 Society for Immunotherapy of Cancer Annual Meeting demonstrated that the profile of its novel HER2-targeted antigen binding domain is unique and differentiated from that of trastuzumab, exhibiting similar potency with greater specificity for cancer cells expressing HER2. The Phase 1 study is designed to assess the safety, pharmacokinetics, and activity of a single dose of FT825 / ONO-8250 as monotherapy and in combination with monoclonal antibody therapy in patients with advanced solid tumors.

FT522 iPSC-derived CAR NK Cell Program

- **First Patient Treated with ADR-armed, CD19-targeted CAR NK Cell Product Candidate.** FT522 is the Company's first product candidate incorporating its proprietary Alloimmune Defense Receptor (ADR) technology, which is designed to reduce or eliminate the need for administration of intense chemotherapy conditioning to patients receiving cell therapies. The multi-center, Phase 1 clinical trial of FT522 in patients with relapsed / refractory B-cell lymphoma is currently enrolling patients in the first three-dose cohort at 300 million cells per dose of Regimen A, which includes administration of chemotherapy conditioning. Subject to clearance of dose-limiting toxicities at this first dose level of Regimen A, enrollment is expected to commence in the first three-dose cohort at 300 million cells per dose of Regimen B without administration of chemotherapy conditioning.
- **Preclinical Studies Ongoing to Support Expansion into Autoimmunity**. The Company is conducting a preclinical assessment of the potential for FT522 to induce CD19+ B-cell depletion across a range of autoimmune diseases, including without administration of intense chemotherapy conditioning to patients. In a disseminated Nalm6 leukemia model comprised of CD19+ target cells resistant to T-cell killing, ADR-armed, CD19-targeted CAR NK cells exhibited robust killing *in vivo* of CD19+ target cells in the presence of alloreactive T cells, suggesting that FT522 has the potential to deplete

CD19+ B cells without administration of intense chemotherapy conditioning to patients. Additional preclinical studies are ongoing with FT522 in combination with monoclonal antibody therapy to assess the potential depletion of both CD19+ B-cell and CD38+ plasma-cell autoantibody-producing lineages.

FT576 iPSC-derived CAR NK Cell Program

- **Dose Escalation Ongoing in Phase 1 Multiple Myeloma Study.** The Company's multi-center, Phase 1 clinical trial of FT576, its BCMA-targeted CAR NK cell product candidate, is currently accruing patients with relapsed / refractory multiple myeloma in three-dose treatment cohorts as monotherapy as well as in combination with CD38-targeted monoclonal antibody. Using a standard three-day chemotherapy conditioning regimen, the Company has treated six patients at 1 billion cells per dose, with no dose-limiting toxicities and no reports of any grade of CRS, ICANS or GvHD. The study is currently enrolling patients at 2.5 billion cells per dose. Any further clinical development of FT576 for the treatment of multiple myeloma will be determined by the Company based on safety and activity at these higher dose levels.

Fourth Quarter 2023 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of December 31, 2023 were $316.2 million.
- **Total Revenue:** Revenue was $1.7 million for the fourth quarter of 2023, 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 fourth quarter of 2023, GAAP operating expenses were $49.8 million, including research and development expenses of $31.8 million and general and administrative expenses of $17.9 million. Such amounts included $9.5 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 98.6 million, and preferred shares outstanding were 2.8 million, as of December 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, Monday, February 26, 2024 at 5:00 p.m. ET to review financial and operating results for the quarter and full year ended December 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

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 disorders. 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 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 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 December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 1,676	$ 44,356	$ 63,533	$ 96,300
Operating expenses:				
Research and development	31,816	87,191	172,596	320,454
General and administrative	17,935	21,584	81,448	84,232
Total operating expenses	49,751	108,775	254,044	404,686
Loss from operations	(48,075)	(64,419)	(190,511)	(308,386)
Other income (expense):				
Interest income	4,414	2,880	17,186	5,842
Change in fair value of stock price appreciation milestones	(645)	5,176	2,515	20,307
Other income	184	—	9,882	516
Total other income (expense), net	3,953	8,056	29,583	26,665
Net loss	$ (44,122)	$ (56,363)	$ (160,928)	$ (281,721)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities, net	514	1,399	1,869	(1,092)
Comprehensive loss	$ (43,608)	$ (54,964)	$ (159,059)	$ (282,813)
Net loss per common share, basic and diluted	$ (0.45)	$ (0.58)	$ (1.64)	$ (2.91)
Weighted–average common shares used to compute basic and diluted net loss per share	98,613,726	97,220,972	98,411,162	96,826,058

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 41,870	$ 61,333
Accounts receivable	1,826	38,480
Short-term investments	273,305	374,894
Prepaid expenses and other current assets	14,539	27,367
Total current assets	331,540	502,074
Long-term investments	980	4,942
Operating lease right-of-use asset	61,675	66,069
Other long-term assets	112,022	132,476
Total assets	$ 506,217	$ 705,561
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 32,233	$ 62,197
Deferred revenue	685	42,226
CIRM award liability	—	4,000
Operating lease liability, current portion	6,176	5,628
Total current liabilities	39,094	114,051
Operating lease liability, net of current portion	97,360	103,710
Stock price appreciation milestones	1,346	3,861
Stockholders' equity	368,417	483,939
Total liabilities and stockholders' equity	$ 506,217	$ 705,561

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