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): November 08, 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 November 8, 2023, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 8, 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: November 8, 2023

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

Fate Therapeutics Reports Third Quarter 2023 Financial Results and Business Updates

Phase 1 Study Open for Enrollment of FT522 ADR-armed, CD19-targeted CAR NK Cell Program for B-cell Lymphoma; Dose Escalation Designed to Assess 3-dose Treatment Schedule with and without Conditioning Chemotherapy

IND Application Cleared by FDA for FT825/ONO-8250 CAR T-cell Program for Solid Tumors; Incorporates Seven Synthetic Controls including Novel Cancer-specific CAR Targeting HER2

iPSC-derived CAR T-cell Product Platform Expanded into Autoimmunity; IND Application Cleared by FDA for FT819 CD19-targeted 1XX CAR T-cell Program for Systemic Lupus Erythematosus

$350 Million in Cash, Cash Equivalents, and Investments to Support Runway into 2H25

San Diego, CA – November 8, 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 third quarter ended September 30, 2023.

“We achieved several key milestones for our iPSC product platform in oncology and autoimmunity, creating additional opportunities to generate new clinical data across multiple programs during 2024,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We have initiated patient enrollment in our Phase 1 study of FT522, our ADR-armed, CD19-targeted CAR NK cell program, where we intend to assess FT522 with and without conditioning chemotherapy in patients with B-cell lymphoma. In addition, our IND application was cleared by the FDA for FT825/ONO-8250 in solid tumors under our collaboration with ONO Pharmaceutical, which multiplexed-engineered CAR T-cell program incorporates seven synthetic controls of cell function including a novel cancer-specific binding domain targeting HER2. Finally, I am pleased to announce the expansion of our iPSC product platform into autoimmunity with the clearance by the FDA of our IND application for FT819, our off-the-shelf, CD19-targeted CAR T-cell program, in systemic lupus erythematosus.”

FT522 iPSC-derived CAR NK Cell Program in B-cell Lymphoma

- **Phase 1 Study of ADR-armed, CD19-targeted CAR NK Cell Program Open for Enrollment.** FT522 is the Company’s off-the-shelf, multiplexed-engineered natural killer (NK) cell product candidate that incorporates five synthetic controls of cell function. It is the Company’s first product candidate armed with its proprietary alloimmune defense receptor (ADR) technology, which is comprised of a synthetic engineered receptor targeting 4-1BB expressed on alloreactive immune cells. In preclinical studies, engagement of ADR-armed CAR NK cells with alloreactive immune cells mitigated rejection, promoted cellular proliferation, and increased anti-tumor activity, indicating that ADR-armed CAR NK cells may be effective without requiring administration of intensive conditioning chemotherapy

to patients. The Phase 1 study of FT522 in combination with rituximab for relapsed / refractory B-cell lymphoma (BCL) is designed to assess safety, pharmacokinetics, and activity with and without administration of a standard three-day preconditioning regimen to patients. Enrollment into the first three-dose cohort at 300 million cells per dose has been initiated. The Company is also assessing in preclinical studies the potential of FT522 to induce benefit across a range of autoimmune diseases.

FT825/ONO-8250 iPSC-derived CAR T-cell Program in Solid Tumors

- **IND Application Cleared by FDA for Multiplexed-engineered, CAR T-cell Program Incorporating Seven Novel Synthetic Controls of Cell Function.** 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 that incorporates a novel cancer-specific H_2CasMab-2 CAR targeting HER2 and is designed to overcome unique challenges in treating solid tumors. The Company's Investigational New Drug (IND) application for FT825/ONO-8250 was cleared by the U.S. Food and Drug Administration (FDA) in October for conduct of a Phase 1 study in patients with advanced solid tumors. The dose-escalation schema includes two treatment regimens: single-dose FT825/ONO-8250 as monotherapy; and FT825/ONO-8250 in combination with cetuximab. Novel synthetic controls incorporated into the multiplexed-engineered CAR T-cell product candidate include a CXCR2 receptor to promote cell trafficking, a chimeric TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment, and a high-affinity, non-cleavable CD16a receptor to promote antibody-dependent cellular cytotoxicity. Preclinical data of FT825/ONO-8250, which was presented at the 2023 Society for Immunotherapy of Cancer (SITC) Annual Meeting, demonstrated that the antigen binding profile of H_2CasMab-2 is unique and differentiated from that of trastuzumab, exhibiting similar potency with greater specificity for malignant HER2-expressing cells.

FT819 iPSC-derived CAR T-cell Program in Systemic Lupus Erythematosus and B-cell Malignancies

- **Expansion into Autoimmunity with Phase 1 Study Start-up Ongoing in SLE.** In July, the Company's IND application was cleared by the FDA for clinical investigation of FT819 in patients with systemic lupus erythematosus (SLE), including those with active lupus nephritis (LN) or active SLE without renal involvement. FT819 is the Company's off-the-shelf, iPSC-derived CAR T-cell product candidate that incorporates several novel synthetic controls of cell function 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. The clinical trial is designed to evaluate the safety, pharmacokinetics, anti-B-cell activity of a single dose of FT819 administered following a standard three-day preconditioning regimen. The FT819 Phase 1 protocol received a favorable review by clinical experts of the Protocol Design Committee of Lupus Therapeutics, an affiliate of the Lupus Research Alliance.
- **Phase 1 Study Advancing in Single-dose Escalation Cohorts for B-cell Malignancies.** The Company's landmark Phase 1 clinical trial of FT819 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 in BCL and at 360 million cells in chronic lymphocytic leukemia using a standard three-day preconditioning regimen. Clinical data previously presented by the Company from the first 11 patients with relapsed / refractory BCL 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 immune effector-cell associated neurotoxicity syndrome (ICANS) and mild cytokine release syndrome (CRS).

FT576 iPSC-derived CAR NK Cell Program in Multiple Myeloma

- **Phase 1 Study Accruing Patients in Three-dose Treatment Cohorts.** The Company's Phase 1 study of FT576, its multiplexed-engineered BCMA-targeted CAR NK cell product candidate for relapsed / refractory multiple myeloma, is currently enrolling patients in two, three-dose treatment cohorts at 1 billion cells per dose. The Company has treated three patients as monotherapy as well as two patients in combination with CD38-targeted monoclonal antibody therapy to assess the therapeutic potential of dual-antigen targeting of myeloma cells, with no dose-limiting toxicities reported by investigators in either cohort.

Third Quarter 2023 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of September 30, 2023 were $349.7 million. In addition, as of September 30, 2023, cash receivables from the Company's collaboration with ONO were $1.5 million.
- **Total Revenue:** Revenue was $1.9 million for the third 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 third quarter of 2023, GAAP operating expenses were $53.2 million, including research and development expenses of $34.3 million and general and administrative expenses of $18.9 million. Such amounts included $10.1 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 September 30, 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, November 8, 2023 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 30, 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 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 research and development programs and product candidates, the Company's clinical and product development strategy, the Company's expectations regarding progress and timelines, and the objectives, plans and goals of its collaboration with ONO, and the impact of the Company's expense reduction and projected cash runway. 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 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, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 1,944	$ 14,981	$ 61,857	$ 51,944
Operating expenses:				
Research and development	34,275	79,817	140,780	233,263
General and administrative	18,948	21,555	63,513	62,648
Total operating expenses	53,223	101,372	204,293	295,911
Loss from operations	(51,279)	(86,391)	(142,436)	(243,967)
Other income (expense):				
Interest income	4,697	1,787	12,772	2,962
Change in fair value of stock price appreciation milestones	1,049	891	3,160	15,131
Other Income	363	150	9,698	516
Total other income (expense), net	6,109	2,828	25,630	18,609
Net loss	$ (45,170)	$ (83,563)	$ (116,806)	$ (225,358)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	88	128	1,355	(2,491)
Comprehensive loss	$ (45,082)	$ (83,435)	$ (115,451)	$ (227,849)
Net loss per common share, basic and diluted	$ (0.46)	$ (0.86)	$ (1.19)	$ (2.33)
Weighted–average common shares used to compute basic and diluted net loss per share	98,568,012	97,023,506	98,342,898	96,692,974

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 33,334	$ 61,333
Accounts receivable	1,538	38,480
Short-term investments	316,400	374,894
Prepaid expenses and other current assets	12,902	27,367
Total current assets	364,174	502,074
Long-term investments	—	4,942
Operating lease right-of-use asset	62,721	66,069
Other long-term assets	116,893	132,476
Total assets	$ 543,788	$ 705,561
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 34,246	$ 62,197
Deferred revenue, current portion	1,110	42,226
CIRM award liability, current portion	—	4,000
Operating lease liability, current portion	5,977	5,628
Total current liabilities	41,333	114,051
Operating lease liability, net of current portion	98,977	103,710
Stock price appreciation milestones, net of current portion	701	3,861
Stockholders' equity	402,777	483,939
Total liabilities and stockholders' equity	$ 543,788	$ 705,561

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