

**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): August 08, 2023

FATE THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36076
(Commission File Number)

65-1311552
(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 August 8, 2023, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 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: August 8, 2023

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



Fate Therapeutics Reports Second Quarter 2023 Financial Results and Business Updates

Phase 1 Study Start-up Ongoing for 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

2H23 IND Submission Planned under ONO Collaboration for FT825/ONO-8250; HER2-targeted CAR T-cell Program Incorporates Seven Novel Synthetic Controls Designed to Overcome Unique Challenges in Treating Solid Tumors

Dose Escalation Ongoing in Phase 1 Studies of FT819 CD19-targeted 1XX CAR T-cell Program for B-cell Malignancies and of FT576 BCMA-targeted CAR NK Cell Program for Multiple Myeloma

Ended 2Q23 with \$385 Million in Cash, Cash Equivalents, and Investments Supporting Runway into 2H25

San Diego, CA – August 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 second quarter ended June 30, 2023.

“We have shown great resilience in advancing our most innovative and differentiated programs while reducing expenses during the first six months of 2023, creating an operating runway into the second half of 2025 that enables us to achieve key milestones across our pipeline,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We have commenced Phase 1 study start-up activities for our FT522 ADR-armed, CD19-targeted CAR NK cell program for B-cell lymphoma, where we intend to assess FT522 with and without administration of conditioning chemotherapy to patients. We have also initiated GMP manufacturing of FT825/ONO-8250 under our solid tumor collaboration with ONO Pharmaceutical, and plan to submit an IND application in the second half of 2023 for this multiplexed-engineered, HER2-targeted CAR T-cell program. Finally, we continue to preclinically assess the potential of our off-the-shelf, iPSC-derived cellular immunotherapies to selectively target and durably deplete pathogenic immune cells, and are evaluating opportunities for clinical expansion into autoimmunity.”

NK Cell Programs

- **Phase 1 Start-up Ongoing for FT522 ADR-armed, CD19-targeted CAR NK Cell Program.** FT522 is the Company’s off-the-shelf, multiplexed-engineered, induced pluripotent stem cell (iPSC)-derived 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 and is

designed to promote anti-tumor activity without requiring administration of intensive conditioning chemotherapy to patients. In May, the U.S. Food and Drug Administration (FDA) allowed the Company's Investigational New Drug (IND) application for the clinical investigation of FT522 in combination with CD20-targeted monoclonal antibody (mAb) therapy in patients with relapsed / refractory B-cell lymphoma. The dose-escalation stage of the study is designed to assess the safety and activity of FT522 with and without administration of intensive conditioning chemotherapy to patients. The Company is conducting Phase 1 study start-up activities at multiple sites, and plans to initiate patient enrollment with a three-dose treatment schedule at 300 million cells per dose. The Company is also currently evaluating in preclinical studies the potential of FT522 to induce an immunologic reset in patients with autoimmune disorders by selectively targeting and durably depleting pathogenic immune cells, including disease-causing B cells, plasma cells, and auto-reactive T cells.

- **FT576 BCMA-targeted CAR NK Cell Program Accruing Patients in Three-dose Treatment Cohorts.** 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 patients in two, three-dose treatment cohorts at 1 billion cells per dose. The Company has treated the first patient as monotherapy, and has also treated the first patient in combination with CD38-targeted mAb to assess the therapeutic potential of dual-antigen targeting of myeloma cells. Patient enrollment in each of the three-dose treatment cohorts is proceeding independently.

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 is the first-ever clinical investigation of a T-cell product candidate manufactured from a clonal master iPSC line. FT819 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 Company is currently enrolling patients in single-dose treatment cohorts at 540 million cells in B-cell lymphoma and at 360 million cells in chronic lymphocytic leukemia.
- **2H23 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 that incorporates seven novel synthetic controls designed to enhance effector cell function and overcome unique challenges in treating solid tumors. The Company is currently conducting IND-enabling activities and GMP manufacturing of FT825/ONO-8250, and plans to submit an IND application to the FDA in the second half of 2023 to jointly conduct 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 a novel HER2-targeted binding domain with a differentiated activity profile, a synthetic CXCR2 receptor to promote cell trafficking, a synthetic TGF β receptor to redirect immunosuppressive signals in the tumor microenvironment, and a synthetic interleukin-7 receptor fusion protein to enhance T-cell function.

Second Quarter 2023 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of June 30, 2023 were \$385.2 million. In addition, as of June 30, 2023, cash receivables from the Company's collaboration with ONO were \$2.8 million.
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- **Total Revenue:** Revenue was \$0.9 million for the second 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 second quarter of 2023, GAAP operating expenses were \$63.5 million, including research and development expenses of \$40.9 million and general and administrative expenses of \$22.6 million. Such amounts included \$12.9 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 98.5 million, and preferred shares outstanding were 2.8 million, as of June 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, Tuesday, August 8, 2023 at 5:00 p.m. ET to review financial and operating results for the quarter ended June 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 product candidates, the Company's clinical and product development strategy, the Company's plans to submit an IND application for its FT825/ONO-8250 HER2-targeted CAR T-cell solid tumor program under 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 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ 933	\$ 18,549	\$ 59,913	\$ 36,963
Operating expenses:				
Research and development	40,876	81,307	106,505	153,446
General and administrative	22,622	20,351	44,565	41,093
Total operating expenses	63,498	101,658	151,070	194,539
Loss from operations	(62,565)	(83,109)	(91,157)	(157,576)
Other income (expense):				
Interest income	4,381	757	8,075	1,175
Change in fair value of stock price appreciation milestones	393	5,881	2,111	14,240
Other Income	5,036	366	9,335	366
Total other income (expense), net	9,810	7,004	19,521	15,781
Net loss	\$ (52,755)	\$ (76,105)	\$ (71,636)	\$ (141,795)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	59	(531)	1,267	(2,619)
Comprehensive loss	\$ (52,696)	\$ (76,636)	\$ (70,369)	\$ (144,414)
Net loss per common share, basic and diluted	\$ (0.54)	\$ (0.79)	\$ (0.73)	\$ (1.47)
Weighted-average common shares used to compute basic and diluted net loss per share	98,400,355	96,704,413	98,228,476	96,524,968

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,802	\$ 61,333
Accounts receivable	2,833	38,480
Short-term investments	331,133	374,894
Prepaid expenses and other current assets	11,414	27,367
Total current assets	<u>392,182</u>	<u>502,074</u>
Long-term investments	7,291	4,942
Operating lease right-of-use asset	63,743	66,069
Other long-term assets	121,541	132,476
Total assets	<u>\$ 584,757</u>	<u>\$ 705,561</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 36,975	\$ 62,197
Deferred revenue	1,929	42,226
CIRM award liability, current portion	—	4,000
Operating lease liability, current portion	5,786	5,628
Total current liabilities	<u>44,690</u>	<u>114,051</u>
Operating lease liability, net of current portion	100,562	103,710
Stock price appreciation milestones	1,750	3,861
Stockholders' equity	437,755	483,939
Total liabilities and stockholders' equity	<u>\$ 584,757</u>	<u>\$ 705,561</u>

Contact:

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