

**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 6, 2019

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
(I.R.S. Employer
Identification No.)

**3535 General Atomics Court, Suite 200
San Diego, CA 92121**
(Address of principal executive offices, including zip code)

(858) 875-1800
(Registrant's telephone number, including area code)

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 6, 2019, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2019. 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 6, 2019

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 hereunto duly authorized.

Date: August 6, 2019

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



Fate Therapeutics Reports Second Quarter 2019 Financial Results and Highlights Operational Progress

No FT500 DLTs Reported at Second Cell Dose Level in Monotherapy Arm or at First Cell Dose Level in Checkpoint Inhibitor Combination Arm in Solid Tumor Study

Successfully Completed FT516 GMP Production and Product Release for Initiation of First-ever Clinical Trial of Engineered iPSC-derived Cell Product

IND Application Submitted for FT596, an Off-the-Shelf, Multi-Antigen Targeted, iPSC-derived CAR NK Cell Product Candidate
Foundational U.S. Patent Issued for Off-the-Shelf iPSC-derived CAR T-cell Therapy

San Diego, CA – August 6, 2019 – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, today reported business highlights and financial results for the second quarter ended June 30, 2019.

“The early safety and tolerability signals observed in patients receiving multiple doses of FT500, the first iPSC-derived cell therapy to undergo clinical investigation in the United States, are very encouraging. The ability to cost-effectively mass-produce a universal cell-based cancer immunotherapy, and to safely deliver that therapy ‘on demand’ in multiple doses, has the potential to transform outcomes for many patients,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We continue to be very pleased with the Company’s rapid pace of innovation, product development and leadership in bringing iPSC-derived cell-based immunotherapies engineered with potent anti-tumor functionality to cancer patients. Our first engineered iPSC-derived NK cell product candidate, FT516, is ready for Phase 1 clinical evaluation following successful completion of cGMP production, and the IND application for our multi-antigen targeted CAR19 NK cell product candidate, FT596, has been submitted to the FDA. Additionally, with the renewal of our collaboration with Memorial Sloan Kettering Cancer Center for the development of iPSC-derived T-cell immunotherapies, we are well positioned to continue to lead the field in the development of off-the-shelf CAR T-cell therapy.”

Universal, Off-the-Shelf NK Cell Cancer Immunotherapy Clinical Programs

- **No DLTs Reported at 300M Cell Dose Level in FT500 Monotherapy Arm.** The first three patients with advanced solid tumors have been treated with multiple doses of FT500, the Company’s universal, off-the-shelf natural killer (NK) cell product candidate derived from a clonal master induced pluripotent stem cell (iPSC) line, at the second dose level in the study’s monotherapy arm. All three patients received three weekly doses of FT500 at 300 million cells per dose in an
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outpatient setting, which treatment cycle was well-tolerated with no dose-limiting toxicities (DLTs) and no FT500-related serious adverse events reported by investigators. All three subjects were eligible to receive a second, multi-dose treatment cycle of FT500 at 300 million cells per dose.

- **No DLTs Reported at 100M Cell Dose Level in FT500 ICI Combination Arm.** The first three patients with advanced solid tumors have been treated with multiple doses of FT500 in combination with immune checkpoint inhibitor (ICI) in the study's combination arm. All three patients received three weekly doses of FT500 at 100 million cells per dose in an outpatient setting, which treatment cycle was well-tolerated with no dose-limiting toxicities and no FT500-related serious adverse events reported by investigators. All three subjects were eligible to receive a second, multi-dose treatment cycle of FT500 at 100 million cells per dose in combination with ICI.
- **FT516 cGMP Production Completed and Product Released for Clinical Trial Initiation.** The Company completed final product release testing for FT516, a universal, off-the-shelf NK cell product candidate derived from a clonal master iPSC line engineered to express a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor. Starting with a single cryopreserved vial from a master engineered iPSC bank, hundreds of cryopreserved doses of FT516 were produced in a single cGMP campaign at a low cost per dose. The cryopreserved FT516 cell product met stringent post-thaw release specifications, including identity, purity, viability and functional activity. The Company is currently initiating clinical investigation of FT516 as a monotherapy for the treatment of acute myeloid leukemia and in combination with CD20-directed monoclonal antibodies for the treatment of B-cell lymphoma. FT516 is the first-ever cell product in the world derived from a genetically engineered pluripotent stem cell to be cleared for clinical investigation.

Universal, Off-the-Shelf NK Cell and T-cell Cancer Immunotherapy Preclinical Pipeline

- **Submitted IND for FT596 Multi-Antigen Targeted CAR NK Cell.** FT596 is the Company's first universal, off-the-shelf chimeric antigen receptor (CAR) NK cell product candidate, and is uniquely designed to engage multiple tumor-associated antigens expressed on cancer cells for best-in-class activity. The product candidate is derived from a master iPSC line engineered to express three functional anti-tumor components: a proprietary CAR targeting the B-cell antigen CD19; a novel hnCD16 Fc receptor for augmented antibody-dependent cellular cytotoxicity; and a unique IL-15 receptor fusion for enhanced NK cell activity. The Company submitted its Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for clinical investigation of FT596 as a monotherapy and in combination with monoclonal antibody therapy for the treatment of subjects with advanced B-cell lymphomas and advanced chronic lymphocytic leukemia.
 - **Renewed iPSC-derived T-cell Collaboration with MSK.** Under its collaboration with Memorial Sloan Kettering Cancer Center (MSK) led by Michel Sadelain, M.D., Ph.D., Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair, the Company is currently conducting IND-enabling activities for FT819, its first universal, off-the-shelf CAR T-cell product candidate. FT819 is derived from a clonal master engineered iPSC line having complete elimination of T-cell receptor (TCR) expression and insertion of a novel 1XX CAR targeting CD19 into the T-cell receptor alpha (TRAC) locus. The three-year renewal extends the Company's exclusive collaboration with Dr. Sadelain for the research and development of iPSC-derived T-cell product candidates.
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Corporate Highlights

- **Received New U.S. Patent for CAR-encoded iPSCs.** In May 2019, the U.S. Patent and Trademark Office granted to the Company a patent foundational to off-the-shelf, iPSC-derived CAR T-cell therapy. U.S. Patent Number 10,287,606, entitled "Genomic Engineering of Pluripotent Cells," covers iPSCs having a CAR construct encoded into the TRAC locus and an endogenous TCR alpha gene knocked out. The complete elimination of the endogenous TCR gene is critical in allogeneic CAR T-cell therapy to ensure the prevention of graft-versus-host disease, a life-threatening disease that can occur when donor T-cells attack a patient's healthy tissue.
- **Expanded Board of Directors.** In July 2019, the Company appointed Dr. Shefali Agarwal to its Board of Directors. Dr. Agarwal has nearly two decades of leadership experience across clinical development, medical research, clinical operations, regulatory, and medical affairs in oncology, and is currently the Chief Medical Officer of Epizyme, Inc., a clinical-stage company developing novel epigenetic therapies for cancer and other serious diseases.

Second Quarter 2019 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of June 30, 2019 were \$162.0 million, compared to \$201.0 million as of December 31, 2018. The decrease was driven primarily by the Company's use of cash to fund operating activities.
- **Total Revenue:** Revenue was \$2.8 million for the second quarter of 2019, compared to \$1.0 million for the same period in 2018. Revenue was derived primarily from the Company's collaboration with Ono Pharmaceutical.
- **R&D Expenses:** Research and development expenses were \$21.6 million for the second quarter of 2019, compared to \$16.8 million for the same period in 2018. The increase in R&D expenses was attributable primarily to an increase in employee compensation, including share-based compensation, and in expenses associated with the clinical development and manufacture of the Company's product candidates and the conduct of our research activities including under our collaboration agreements.
- **G&A Expenses:** General and administrative expenses were \$5.3 million for the second quarter of 2019, compared to \$3.8 million for the same period in 2018. The increase in G&A expenses was attributable primarily to an increase in employee compensation, including share-based compensation.
- **Shares Outstanding:** Common shares outstanding were 65.3 million as of June 30, 2019 and 64.7 million as of December 31, 2018. Preferred shares outstanding as of June 30, 2019 and December 31, 2018 were 2.8 million, each of which is convertible into five shares of common stock.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Tuesday, August 6, 2019 at 5:00 p.m. ET to review financial and operating results for the quarter ended June 30, 2019. In order to participate in the conference call, please dial 877-303-6235 (domestic) or 631-291-4837 (international) and refer to conference ID 3898842. The live webcast can be accessed under "Events & Presentations" in the

Investors & Media 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, engineered, homogeneous cell products that can be administered in repeat doses to mediate more effective pharmacologic activity, including in combination with cycles of other cancer treatments. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event and selecting a single iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf for patient treatment. As a result, the Company's platform is uniquely capable of overcoming numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is fraught with batch-to-batch and cell-to-cell variability that can affect safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 200 issued patents and 150 pending patent applications.

About FT500

FT500 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line. Despite the clinical benefit conferred by approved immune checkpoint inhibitor (ICI) therapy against a variety of tumor types, these therapies are not curative and, in most cases, patients either fail to respond or progress on these agents. One common mechanism of resistance to ICI therapy is associated with loss-of-function mutations in genes critical for antigen presentation. A potential strategy to overcome resistance is through the administration of allogeneic NK cells, which have the inherent capability to recognize and directly kill tumor cells with these mutations. FT500 is being investigated in an open-label, multi-dose Phase 1 clinical trial for the treatment of advanced solid tumors (clinicaltrials.gov ID number NCT03841110). The study is designed to assess the safety and activity of three once-weekly doses of FT500 as a monotherapy and in combination with one of three FDA-approved ICI therapies – nivolumab, pembrolizumab or atezolizumab – in patients that have failed prior checkpoint inhibitor therapy. Patients who are clinically stable following the first cycle of FT500 treatment are eligible to receive a second treatment cycle of three additional once-weekly doses of FT500.

About FT516

FT516 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 to express a novel high-affinity (158V), non-cleavable CD16 (hnCD16) Fc receptor. CD16 mediates antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells. CD16 occurs in two variants, either with high (158V) or low (158F) affinity for the Fc

domain of IgG1 antibodies. Numerous clinical studies with FDA-approved tumor-targeting antibodies, including rituximab, trastuzumab and cetuximab, have demonstrated that patients homozygous for the CD16 high-affinity variant, which is present in approximately 15% of patients, have improved clinical outcomes. In addition, ADCC is dependent on NK cells maintaining active levels of CD16 expression, and the expression of CD16 on NK cells has been shown to undergo considerable down-regulation in cancer patients, which can significantly inhibit anti-tumor activity. FT516 incorporates a novel CD16 Fc receptor, which has been modified to prevent its down-regulation and augment its binding to tumor-targeting antibodies for enhanced ADCC. The FDA has allowed investigation of FT516 in an open-label, multi-dose Phase 1 clinical trial as a monotherapy for the treatment of acute myeloid leukemia and in combination with CD20-directed monoclonal antibodies for the treatment of B-cell lymphoma (clinicaltrials.gov ID number NCT04023071).

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for cancer and immune disorders. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease, and a myeloid-derived suppressor cell immunotherapy for promoting immune tolerance in patients with immune disorders. 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 and sufficiency of its cash and cash equivalents to fund its operations, as well as statements regarding the advancement of and plans related to its product candidates, clinical studies and preclinical research and development programs, the Company's progress, plans and timelines for the manufacture and clinical investigation of its product candidates, the timing for the Company's receipt of data from its clinical trials and preclinical studies, the Company's development and regulatory strategy, and the therapeutic and market potential of the Company's product candidates. 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 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 of, or enrollment of subjects in, any clinical studies, 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 or to support regulatory approval, difficulties or delays in subject enrollment in current 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), and the risk that the Company's expenditures may exceed current expectations for a variety of reasons. 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.

Availability of Other Information about Fate Therapeutics, Inc.

Investors and others should note that the Company routinely communicates with investors and the public using its website (www.fatetherapeutics.com) and its investor relations website (ir.fatetherapeutics.com) including, without limitation, through the posting of investor presentations, SEC filings, press releases, public conference calls and webcasts on these websites. The information posted on these websites could be deemed to be material information. As a result, investors, the media, and others interested in Fate Therapeutics are encouraged to review this information on a regular basis. The contents of the Company's website, or any other website that may be accessed from the Company's website, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
operation revenue	\$ 2,817	\$ 1,027	\$ 5,449	\$ 2,053
Operating expenses:				
Research and development	21,631	16,816	39,359	28,292
General and administrative	5,270	3,816	10,620	7,420
Operating expenses	26,901	20,632	49,979	35,712
Income from operations	(24,084)	(19,605)	(44,530)	(33,659)
Other income (expense):				
Interest income	1,015	376	2,106	707
Interest expense	(409)	(425)	(814)	(837)
Other income (expense), net	606	(49)	1,292	(130)
Income from operations	\$ (23,478)	\$ (19,654)	\$ (43,238)	\$ (33,789)
Other comprehensive income (loss):				
Realized gain (loss) on available-for-sale securities, net	93	(2)	95	(12)
Other comprehensive loss	\$ (23,385)	\$ (19,656)	\$ (43,143)	\$ (33,801)
Net loss per common share, basic and diluted	\$ (0.36)	\$ (0.37)	\$ (0.66)	\$ (0.64)
Weighted-average common shares used to compute basic and diluted net loss per share	65,213,364	53,130,518	65,067,801	52,947,926

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 71,435	\$ 190,514
Short-term investments and related maturity receivables	90,573	10,493
Accounts receivable	—	500
Prepaid expenses and other current assets	3,170	3,689
Total current assets	165,178	205,196
Operating lease right-of-use asset	23,560	—
Other long-term assets	11,139	7,836
Total assets	\$ 199,877	\$ 213,032
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,244	\$ 15,131
Deferred revenue, current portion	5,049	7,588
CIRM award liability, current portion	2,106	2,106
Operating lease liability, current portion	1,572	—
Long-term debt, current portion	5,447	2,438
Total current liabilities	29,418	27,263
Deferred revenue, net of current portion	5,244	7,500
CIRM award liability, net of current portion	1,404	1,404
Operating lease liability, net of current portion	26,098	—
Long-term debt, net of current portion	9,469	12,446
Other long-term liabilities	718	3,950
Stockholders' equity	127,526	160,469
Total liabilities and stockholders' equity	\$ 199,877	\$ 213,032

Contact:

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