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): May 7, 2019

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)**	**(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))

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. ☐

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

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 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.

Exhibit No.	**Description**
99.1	Press release dated May 7, 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: May 7, 2019

FATE THERAPEUTICS, INC.

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

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

First-ever Patient Treated in U.S. with an iPSC-derived Cell Therapy Successfully Advances through Six-dose Treatment Course

No Dose-Limiting Toxicities or Serious Adverse Events Reported in Initial Cohort of FT500 iPSC-derived NK Cell Cancer Immunotherapy Patients

FT500 Clinical Trial Now Open for Enrollment in Checkpoint Inhibitor Combination Arm for Treatment of Advanced Solid Tumors

San Diego, CA – **May 7, 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 first quarter ended March 31, 2019.

"These past several months have been particularly inspiring for the Company, as we have delivered on our multi-year journey to be the first to bring iPSC-derived cell products to patients with cancer. We believe the ability to cost-effectively mass-produce cell-based cancer immunotherapies that can be safely delivered to patients 'on demand' in multiple doses has the potential to transform outcomes for many patients, especially when combined with therapeutic agents that have complementary mechanisms of action such as checkpoint inhibitors and monoclonal antibodies," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We are very encouraged by the initial observations of safety and tolerability from the three patients who received multiple doses of FT500 in the first dose cohort, and we are excited with the initiation of the multi-dose checkpoint inhibitor combination arm where patients have previously progressed or failed therapy. In addition, we continue to make tremendous progress in advancing additional candidates from our off-the-shelf, iPSC-derived NK cell and T-cell product pipeline toward the clinic, and we look forward to generating initial clinical data with FT516 and FT596 in 2019."

Clinical Programs

- **Landmark Clinical Trial of iPSC-derived Cell Product FT500 Clears Key Safety Hurdle.** 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 first dose level of 100 million cells per dose in the study's monotherapy arm. All three patients received three once-weekly doses of FT500 in an outpatient setting in the first treatment cycle, which was well-tolerated with no dose-limiting toxicities or serious adverse events reported during the initial 28-day observation period. In

accordance with the clinical protocol, all three patients advanced to a second, multi-dose treatment cycle of FT500, which has also been well-tolerated with no dose-limiting toxicities or serious adverse events reported to date. As a result of clearing the first safety hurdle, the Company has commenced patient enrollment at the second dose level of 300 million cells per dose.

- **FT500 Study Opened for Enrollment in Checkpoint Inhibitor Combination Arm.** In April, the Company opened enrollment in the checkpoint inhibitor combination arm of the FT500 clinical trial for the treatment of advanced solid tumors. Multiple doses of FT500 will be administered in combination with either nivolumab, pembrolizumab or atezolizumab in patients whose tumors failed to respond (primary resistance), or progressed following initial response (acquired resistance), with the prior checkpoint inhibitor therapy.
- **Showcased GMP Manufacturing Data for FT500 Production at ASGCT.** At the American Society of Gene & Cell Therapy (ASGCT) 22nd Annual Meeting in April, the Company demonstrated its unmatched ability for cGMP mass production of cell-based cancer immunotherapies for off-the-shelf use. Starting with a single cryopreserved vial from the FT500 master iPSC bank, hundreds of cryopreserved doses of FT500 were produced in a single manufacturing campaign at a low cost per dose. The cryopreserved FT500 cell product met stringent post-thaw release specifications, including identity (100% CD45+ hematopoietic cells), purity (98% CD45+CD56+ NK cells), viability and potency, to support shipment to participating clinical sites. FT500 exhibits high levels of expression of key activating receptors (including NKG2D and NKp30/40/46), low levels of expression of checkpoint receptors (including PD-1, LAG-3 and TIGIT), and secretes high levels of cytolytic proteins (such as perforin and granzyme B) in response to challenge with cancer cell lines.
- **Expanded Enrollment of Phase 2 PROTECT Study of ProTmune to 80 Patients.** The randomized, controlled and double-blind Phase 2 PROTECT study has enrolled over 55 patients undergoing allogeneic hematopoietic cell transplant for the treatment of hematologic malignancies. While remaining blinded, the Company has elected to increase the size of the PROTECT study to 80 patients based on strong investigator interest and with the intent to potentially seek regulatory approval of ProTmune using data from the study. The Company expects to complete enrollment of the PROTECT study in 2019 as planned, with data available in 2020 on the study's primary and secondary endpoints.

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

- **Received FDA Clearance of IND Application for First-ever Engineered iPSC-derived Cell Product FT516.** In February 2019, the Company announced that the FDA allowed its IND application 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. FT516 is the first-ever cell product derived from a genetically engineered pluripotent stem cell to be cleared for clinical testing worldwide. A cGMP production run for FT516 has been completed, and final product release testing is ongoing. The Company intends to clinically investigate FT516 for the treatment of relapsed / refractory hematologic malignancies including in combination with certain FDA-approved monoclonal antibody therapies.

- **Generated Clonal Master Engineered iPSC Bank for FT596 Dual Antigen-targeted CAR NK Cell.** FT596 is the Company's universal, off-the-shelf chimeric antigen receptor (CAR) NK cell product candidate that expresses a proprietary CD19-targeted CAR, a novel hnCD16 Fc receptor for augmented antibody-dependent cellular cytotoxicity (ADCC) and a unique IL-15 receptor fusion for enhanced NK cell activity. The FT596 clonal master iPSC bank was derived from a single iPSC, which was specifically selected based on a series of critical attributes including characterization of the genomic integration sites of the engineered elements, confirmation of genomic stability, demonstration of highly efficient and reproducible production of the product candidate, and robust post-cryopreservation viability and multi-purpose functional activity of the product candidate. The Company expects to submit an IND application to the FDA in mid-2019 for clinical investigation of FT596.

Corporate Highlights

- **Expanded Board of Directors.** In March 2019, the Company appointed Karin Jooss, Ph.D. to its Board of Directors. Dr. Jooss has more than 20 years of experience in oncology and immunology research and development and is currently the Executive Vice President of Research and Chief Scientific Officer of Gritstone Oncology, Inc., a clinical-stage biotechnology company developing next-generation cancer immunotherapies targeting tumor-specific neoantigens.
- **Expanded Clinical Development and Translation Leadership Team.** Sarah Cooley, M.D., M.S. joined the Company in February 2019 as Senior Vice President, Clinical Translation, and Yu-Waye (Wayne) Chu, M.D. joined the Company in April 2019 as Vice President, Clinical Development. Dr. Cooley brings to Fate Therapeutics more than 12 years of leadership in the field of NK cell clinical research and development, having most recently served as Associate Professor of Medicine in the Division of Hematology, Oncology and Transplantation at the University of Minnesota. Dr. Chu brings extensive experience in the development of cancer immunotherapies from Genentech, where he most recently served in Product Development Oncology as global development leader of mosunetuzumab, a full-length T cell-dependent bispecific CD20/CD3 antibody.

First Quarter 2019 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of March 31, 2019 were $183.0 million, compared to $201.0 million as of December 31, 2018. The decrease was primarily driven by the Company's use of cash to fund operating activities.
- **Total Revenue:** Revenue was $2.6 million for the first quarter of 2019, compared to $1.0 million for the same period in 2018. Revenue was derived from the Company's collaborations with Ono Pharmaceutical and Juno Therapeutics.
- **R&D Expenses:** Research and development expenses were $17.7 million for the first quarter of 2019, compared to $11.5 million for the same period in 2018. The increase in R&D expenses was primarily attributable to an increase in expenses associated with the preclinical and clinical development of the Company's product pipeline and in employee compensation, including share-based compensation, associated with growth in headcount.

- **G&A Expenses:** General and administrative expenses were $5.4 million for the first quarter of 2019, compared to $3.6 million for the same period in 2018. The increase in G&A expenses was primarily attributable to an increase in employee compensation, including share-based compensation.
- **Shares Outstanding:** Common shares outstanding were 65.1 million as of March 31, 2019 and 64.7 million as of December 31, 2018. Preferred shares outstanding as of March 31, 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, May 7, 2019 at 5:00 p.m. ET to review financial and operating results for the quarter ended March 31, 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 6444079. 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 to treat many patients. 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 100 issued patents and 100 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 checkpoint inhibitor 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 checkpoint inhibitor 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 checkpoint inhibitor 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 (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.

About ProTmune™

ProTmune™ is an investigational, first-in-class, allogeneic hematopoietic cell graft for the prevention of acute graft-versus-host disease (GvHD) in patients undergoing hematopoietic cell transplantation (HCT) for the treatment of hematologic malignancies. ProTmune is manufactured by pharmacologically modulating a donor-sourced, mobilized peripheral blood graft *ex vivo* with two small molecules (FT1050 and FT4145) to decrease the incidence and severity of acute GvHD while maintaining the anti-leukemia activity of the graft. ProTmune has been granted Orphan Drug and Fast Track Designations by the U.S. Food and Drug Administration, and Orphan Medicinal Product Designation by the European Commission. ProTmune is currently being investigated in a randomized, controlled and double-blind Phase 2 clinical trial in adult subjects with hematologic malignancies undergoing matched unrelated donor HCT.

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 is pioneering the development of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline is comprised of NK cell and T-cell cancer immunotherapies, with a focus on developing universal, off-the-shelf cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens. The Company's first iPSC-derived NK cell product candidates include FT500, which is currently being clinically investigated for the treatment of advanced solid tumors, and FT516, for which the

Company is preparing to initiate clinical investigation for the treatment of certain hematologic malignancies. The Company's immuno-regulatory pipeline includes 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 March 31,	
	2019	**2018**
Collaboration revenue	$ 2,632	$ 1,026
Operating expenses:		
Research and development	17,728	11,476
General and administrative	5,350	3,604
Total operating expenses	23,078	15,080
Loss from operations	(20,446)	(14,054)
Other income (expense):		
Interest income	1,091	331
Interest expense	(405)	(412)
Total other income (expense), net	686	(81)
Net loss	$ (19,760)	$ (14,135)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities, net	2	(10)
Comprehensive loss	$ (19,758)	$ (14,145)
Net loss per common share, basic and diluted	$ (0.30)	$ (0.27)
Weighted–average common shares used to compute basic and diluted net loss per share	64,920,621	52,763,306

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 183,033	$ 190,514
Accounts receivable	500	500
Short-term investments and related maturity receivables	—	10,493
Prepaid expenses and other current assets	2,897	3,689
Total current assets	186,430	205,196
Operating lease right-of-use asset	23,955	—
Other long-term assets	10,480	7,836
Total assets	$ 220,865	$ 213,032
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,317	$ 15,131
CIRM award liability, current portion	2,106	2,106
Long-term debt, current portion	3,941	2,438
Deferred revenue, current portion	6,576	7,588
Operating lease liability, current portion	1,200	—
Total current liabilities	29,140	27,263
Long-term debt, net of current portion	10,958	12,446
CIRM award liability, net of current portion	1,404	1,404
Operating lease liability, net of current portion	26,517	—
Deferred revenue, net of current portion	6,380	7,500
Other long-term liabilities	629	3,950
Stockholders' equity	145,837	160,469
Total liabilities and stockholders' equity	$ 220,865	$ 213,032

Contact:
Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina@sternir.com