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 5, 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))

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 5, 2019, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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.

Exhibit No.	Description
99.1	Press release dated November 5, 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: November 5, 2019

FATE THERAPEUTICS, INC.

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

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

First Patients Treated with FT516, an Off-the-Shelf NK Cell Cancer Immunotherapy for AML and for B-cell Lymphoma in Combination with Rituximab

Received FDA Clearance of IND Application for FT596, an Off-the-Shelf, Multi-Antigen Targeted CAR NK Cell Product Candidate

Opened State-of-the-art cGMP Facility Dedicated to Manufacturing iPSC-derived Cell Therapies

$303 Million in Cash & Short-term Investments as of September 30, 2019 following Completion of $173 Million Common Stock Offering

San Diego, CA – **November 5, 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 third quarter ended September 30, 2019.

"We achieved several significant clinical milestones over the past three months including treating the first patients with FT516, the first-ever engineered iPSC-derived cellular immunotherapy, and securing FDA clearance to initiate clinical investigation of FT596, the first-ever cellular immunotherapy engineered to express three active anti-tumor modalities. We also successfully opened our new cGMP facility specifically designed to enable consistent, large-scale, and cost-effective manufacture of allogeneic NK cell and CAR-T cell products using clonal master iPSC lines as a starting cell source," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We look forward to the ASH annual meeting in December, where we have had six abstracts accepted and will be sharing our first-in-human insights into the clinical safety and tolerability of FT500, the first-ever iPSC-derived cell therapy to be administered off-the-shelf in multiple doses over multiple cycles. With the completion of our recent common stock offering in September, we are well-positioned to generate clinical data across our iPSC-derived, cell-based cancer immunotherapy pipeline in 2020."

Clinical Programs

- **First-ever Patient Treatment with Engineered iPSC-derived Cell Product.** In October 2019, two patients at the M Health Fairview University of Minnesota Medical Center were treated with FT516, the Company's 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, non-cleavable CD16 Fc receptor. FT516 is the first-ever cell product in the world derived from a genetically engineered pluripotent stem cell to be administered to patients. The first patient received FT516 in combination with rituximab for the treatment of diffuse large B-cell lymphoma, and the second patient received FT516 as a monotherapy for the treatment of acute myeloid leukemia.

- **Initiated Enrollment at 300M Cell Dose Level in FT500 ICI Combination Arm.** The Company is conducting an open-label, multi-dose Phase 1 clinical trial of FT500, an off-the-shelf NK cell cancer immunotherapy derived from a clonal master iPSC line, for the treatment of advanced solid tumors. The dose-escalating stage of the Phase 1 study is designed to assess the safety and tolerability of administering up to six doses of FT500 as a monotherapy and in combination with immune checkpoint inhibitor (ICI) in an outpatient setting. In the monotherapy arm of the study, three patients have been treated at 100 million cells per dose and five patients have been treated at 300 million cells per dose, with no reported dose-limiting toxicities (DLTs) or FT500-related serious adverse events. Additionally, in the combination arm of the study in patients that have failed prior ICI therapy, three patients have been treated at 100 million cells per dose in combination with ICI therapy, with no reported DLTs or FT500-related serious adverse events. The Company is currently enrolling patients at 300 million cells per dose in the combination arm of the study.
- **Received FDA Clearance of IND Application for FT596.** In September, the U.S. Food and Drug Administration (FDA) allowed the Company's Investigational New Drug (IND) application for FT596, the Company's first off-the-shelf chimeric antigen receptor (CAR) NK cell cancer immunotherapy, which is uniquely designed to engage multiple tumor-associated antigens expressed on cancer cells for best-in-class activity. FT596 is derived from a clonal master iPSC line engineered with three anti-tumor functional modalities: a proprietary CAR optimized for NK cell biology that targets the B-cell antigen CD19; a novel high-affinity, non-cleavable CD16 Fc receptor that is designed to augment antibody dependent cellular cytotoxicity (ADCC); and an IL-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes NK cell activation without the need for systemic cytokine support. Study initiation is underway at multiple clinical sites for the first-in-human Phase 1 clinical trial of FT596 as a monotherapy, in combination with rituximab for the treatment of advanced B-cell lymphoma, and in combination with obinutuzumab for the treatment of chronic lymphocytic leukemia.
- **Completed Enrollment in Phase 2 PROTECT Study of ProTmune.** In October, the Company completed enrollment in the randomized, controlled and double-blinded Phase 2 PROTECT study of ProTmune, the Company's 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 has been granted Orphan Drug and Fast Track Designations by the FDA, and Orphan Medicinal Product Designation by the European Commission.

Corporate Highlights

- **Opened State-of-the-Art cGMP Manufacturing Facility Dedicated to iPSC-derived Cell Therapies.** In September 2019, the Company opened its current Good Manufacturing Practice (cGMP) manufacturing facility for the clinical production of its off-the-shelf NK cell and CAR T-cell product candidates. The Company's facility, located in San Diego, California, is custom designed to use clonal master iPSC lines as a renewable cell source for the manufacture of off-the-shelf allogeneic cell products. The new state-of-the-art facility has been commissioned and qualified, the Company has been issued a drug manufacturing license by the State of California, Department of Health Services, Food and Drug Branch, and the Company has commenced manufacture of certain of its product candidates.
- **Foundational U.S. Patent Issued Covering iPSC-derived CAR T Cells.** In August 2019, the U.S. Patent and Trademark Office issued U.S. Patent No. 10,370,452 covering compositions and uses of effector T cells expressing a CAR, where such T cells are derived from a pluripotent stem cell including an iPSC. The claims of this newly-issued patent are not restricted by the signaling domain of the CAR construct nor by the antigen to which the CAR targets and binds. The patent is expected to expire in 2034, and is owned by Memorial Sloan Kettering Cancer Center (MSK) and is licensed exclusively to Fate Therapeutics for all human therapeutic uses. The Company is currently conducting IND-enabling activities for FT819, its first off-the-shelf, iPSC-derived CAR T-cell product candidate, under its collaboration with MSK.
- **Completed $173 Million Common Stock Offering.** In September 2019, the Company closed an underwritten public offering of 9.9 million shares of its common stock at a public offering price of $17.50 per share.

Third Quarter 2019 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of September 30, 2019 were $302.8 million, compared to $201.0 million as of December 31, 2018. The increase was driven primarily by $162.4 million in net cash proceeds received by the Company from its September 2019 public offering of common stock. These proceeds were offset by the Company's use of cash to fund operating activities.
- **Total Revenue:** Revenue was $2.4 million for the third quarter of 2019, compared to $1.0 million for the same period in 2019. Revenue for the third quarter of 2019 was derived from the Company's collaboration with Ono Pharmaceutical.
- **R&D Expenses:** Research and development expenses were $23.2 million for the third quarter of 2019, compared to $13.6 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 research activities including under the collaboration with Ono Pharmaceutical.
- **G&A Expenses:** General and administrative expenses were $6.3 million for the third quarter of 2019, compared to $4.1 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 75.4 million as of September 30, 2019 and 64.7 million as of December 31, 2018. Preferred shares outstanding as of September 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, November 5, 2019 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 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 4748666. 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 with multiple doses to deliver 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 engineered 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 subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 250 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. The product candidate 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 immune checkpoint inhibitor (ICI) therapies – nivolumab, pembrolizumab or atezolizumab – in patients that have failed prior ICI therapy. Despite the clinical benefit conferred by approved 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.

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 Fc receptor, which has been modified to prevent its down-regulation and enhance its binding to tumor-targeting antibodies. The product candidate is being investigated 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 advanced B-cell lymphoma (clinicaltrials.gov ID number NCT04023071). 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 158V variant, which is present in only about 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.

About FT596
FT596 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 with three anti-tumor functional modalities: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology, which contains a NKG2D transmembrane domain, a 2B4 co-stimulatory domain and a CD3-zeta signaling domain, that targets B-cell antigen CD19; a novel high-affinity 158V, non-cleavable CD16 Fc receptor that has been modified to augment antibody-dependent cellular cytotoxicity by preventing CD16 down-regulation and enhancing CD16 binding to tumor-targeting antibodies; and an IL-15 receptor fusion (IL-15RF) that promotes enhanced NK cell activity. The FDA has allowed investigation of FT596 in an open-label Phase 1 clinical trial as a monotherapy, in combination with rituximab for the treatment of advanced B-cell lymphoma, and in combination with obinutuzumab for the treatment of chronic lymphocytic leukemia. In preclinical studies of FT596, the Company has demonstrated that dual activation of the CAR19 and CD16 receptors, in combination with IL-15RF signaling, convey synergistic anti-tumor activity. Increased degranulation and cytokine release were observed upon dual receptor activation in lymphoma cancer cells as compared to activation of each receptor alone, indicating that multi-antigen engagement may elicit a deeper and more durable response. Additionally, in a mixed cellular composition cytotoxicity assay comprised of CD19+ and CD19- tumor cells, FT596 combined with CD20-directed monoclonal antibody therapy effectively eliminated the heterogeneous population of tumor cells, a result that was not observed with single-antigen targeted CAR19 T cells.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 2,429	$ 1,026	$ 7,878	$ 3,079
Operating expenses:				
Research and development	23,202	13,637	62,561	41,929
General and administrative	6,346	4,081	16,966	11,501
Total operating expenses	29,548	17,718	79,527	53,430
Loss from operations	(27,119)	(16,692)	(71,649)	(50,351)
Other income (expense):				
Interest income	910	339	3,016	1,046
Interest expense	(400)	(429)	(1,214)	(1,266)
Total other income (expense), net	510	(90)	1,802	(220)
Net loss	$ (26,609)	$ (16,782)	$ (69,847)	$ (50,571)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	(42)	1	53	(11)
Comprehensive loss	$ (26,651)	$ (16,781)	$ (69,794)	$ (50,582)
Net loss per common share, basic and diluted	$ (0.40)	$ (0.31)	$ (1.06)	$ (0.95)
Weighted–average common shares used to compute basic and diluted net loss per share	66,929,503	54,185,022	65,695,188	53,364,823

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 249,588	$ 190,514
Accounts receivable	—	500
Short-term investments and related maturity receivables	53,235	10,493
Prepaid expenses and other current assets	2,810	3,689
Total current assets	305,633	205,196
Operating lease right-of-use asset	23,160	—
Other long-term assets	11,414	7,836
Total assets	$ 340,207	$ 213,032
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,558	$ 15,131
Deferred revenue, current portion	3,367	7,588
CIRM award liability, current portion	2,106	2,106
Operating lease liability, current portion	1,632	—
Long-term debt, current portion	13,932	2,438
Total current liabilities	40,595	27,263
Deferred revenue, net of current portion	4,496	7,500
CIRM award liability, net of current portion	1,404	1,404
Operating lease liability, net of current portion	25,670	—
Long-term debt, net of current portion	—	12,446
Other long-term liabilities	—	3,950
Stockholders' equity	268,042	160,469
Total liabilities and stockholders' equity	$ 340,207	$ 213,032

Contact:
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