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): March 2, 2020

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 March 2, 2020, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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 March 2, 2020

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: March 2, 2020

FATE THERAPEUTICS, INC.

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

Fate Therapeutics Reports Fourth Quarter 2019 Financial Results and Operational Progress with 2020 Outlook

Reported Initial Clinical Data from FT500 Phase 1 Study in Advanced Solid Tumors, Supporting Safety and Tolerability of Multi-dose Treatment Paradigm for Off-the-shelf, iPSC-derived NK Cells

First Patients Treated with FT516, the First-ever Engineered iPSC-derived Cellular Immunotherapy, for AML and for B-cell Lymphoma in Combination with Rituximab

Initiated Enrollment of First-in-human Clinical Trial of FT596, the First-ever Cellular Immunotherapy Engineered with Three Active Anti-tumor Modalities

Ended Quarter with $261 Million in Cash, Cash Equivalents and Marketable Securities

San Diego, CA – **March 2, 2020** – 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 fourth quarter ended December 31, 2019.

"In 2019, we made tremendous progress in pioneering the clinical development of off-the-shelf, iPSC-derived cancer immunotherapy. Our FT500 program demonstrated that multiple doses of iPSC-derived NK cells can be delivered off-the-shelf to a patient in a safe manner without patient matching. Additionally, our FT516 program provided initial clinical evidence that engineered iPSC-derived NK cells may confer anti-tumor activity and deliver clinically meaningful benefit to patients. We also showed the unmatched scalability of our proprietary iPSC product platform, having manufactured hundreds of cryopreserved, infusion-ready doses of our iPSC-derived NK cell product candidates at a low cost per dose in our new GMP manufacturing facility," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "In 2020, we look forward to additional clinical data from our FT500 and FT516 programs, and initial clinical data from FT596, our ground-breaking iPSC-derived CAR NK cell product candidate for the treatment of B-cell malignancies designed to overcome many of the limitations inherent in current CAR T-cell immunotherapies. We also expect to begin clinical investigation of our off-the-shelf, iPSC-derived NK cell programs in multiple myeloma with planned IND submissions for FT538, the first-ever CRISPR-edited, iPSC-derived cell therapy, and for FT576, our multi-antigen targeted, CAR-BCMA product candidate. Finally, under our collaboration with Memorial Sloan Kettering, we strive to be the first group in the world to bring off-the-shelf, iPSC-derived CAR T-cell therapy to patients."

Clinical Programs

- **Encouraging Safety, Tolerability and Immunogenicity Data from FT500 Phase 1 Study Announced.** In December, the Company reported initial clinical data from the dose-escalation stage of the FT500 Phase 1 study for the treatment of advanced solid tumors as of a November 28, 2019 data cutoff (n=8

monotherapy; n=4 in combination with checkpoint inhibitor therapy). The multi-dose treatment course, consisting of three once-weekly doses of FT500 over up to two 30-day cycles, was well-tolerated, and there were no dose-limiting toxicities, no FT500-related Grade ≥3 adverse events (AEs) or serious adverse events (SAEs), and no incidents of cytokine release syndrome, neurotoxicity, or graft-versus-host disease, reported in the 12 patients. Additionally, based on assessments of the patients' T-cell compartment and antibody repertoire, an adverse immune response against FT500 was not evident over the multi-dose treatment course. The Company has amended the FT500 clinical protocol to include IL-2 administration to support NK cell activity, and is initiating the dose-expansion stage of the FT500 Phase 1 study in patients who are refractory to, or have relapsed following, checkpoint inhibitor therapy at 300 million cells per dose in combination with the checkpoint inhibitor on which the patient failed or progressed.

- **Initial Patients Treated with FT516, the First-ever Engineered, iPSC-derived Cellular Immunotherapy.** In December, the Company announced that the first two patients were treated with FT516, the Company's off-the-shelf NK cell cancer immunotherapy derived from a clonal master iPSC line engineered to express a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor. Each patient received three once-weekly doses of FT516 over a 30-day cycle, and there were no FT516-related Grade ≥3 adverse events (AEs) or serious adverse events (SAEs), and no incidents of cytokine release syndrome, neurotoxicity, or graft-versus-host disease, reported by investigators. Each patient was eligible to receive a second 30-day cycle of three once-weekly doses of FT516. The FT516 study is an open-label, multi-dose Phase 1 clinical trial as a monotherapy for the treatment of AML and in combination with CD20-directed monoclonal antibodies for the treatment of advanced B-cell lymphoma.
- **FT516 Clinical Investigation Expanded to Solid Tumors.** In January, the Company announced that the U.S. Food and Drug Administration (FDA) allowed its second IND application for FT516, enabling clinical investigation of FT516 in combination with PDL1-, PD1-, EGFR- and HER2-targeting monoclonal antibody (mAb) therapies across a broad range of solid tumors. The Company intends to initially evaluate FT516 in combination with avelumab in patients with advanced solid tumors who are refractory to, or have relapsed following, at least one line of anti-PDL1 mAb therapy. The multi-dose treatment course consists of three once-weekly doses of FT516 over up to two 30-day cycles.
- **Patient Enrollment Initiated in FT596 Phase 1 Study for Advanced B-cell Malignancies.** The Company is currently conducting an open-label Phase 1 clinical trial of FT596, the Company's first off-the-shelf, iPSC-derived chimeric antigen receptor (CAR) NK cell cancer immunotherapy and the first cellular immunotherapy engineered with three active anti-tumor modalities, to be cleared for clinical investigation by the FDA. In addition to a proprietary CAR targeting CD19, FT596 expresses a hnCD16 Fc receptor for coincident targeting of additional tumor-associated antigens expressed on cancer cells, such as CD20, to overcome antigen escape. FT596 also expresses an interleukin-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes survival, proliferation and trans-activation of NK cells and CD8 T cells without the need for systemic cytokine support.
- **FT596 Clinical Supply Successfully Produced in Newly-launched, In-house GMP Facility.** In preparation for Phase 1 initiation, the Company produced over 300 cryopreserved, infusion-ready doses of FT596, at a low cost per dose, in its newly-launched Good Manufacturing Practice (GMP) facility. FT596 met stringent release criteria, and the cryopreserved, infusion-ready doses demonstrate robust cell viability and potency, and exhibit high levels of cell-surface expression of both CAR19 and hnCD16 targeting receptors, upon thaw. The Company's GMP facility, located in San Diego, California, is custom designed to use clonal

master iPSC lines as a renewable cell source for the consistent and scaled manufacture of off-the-shelf NK cell and CAR T-cell products.

Preclinical Pipeline

- **IND-enabling Data Presented for FT538, the First CRISPR-edited, iPSC-derived Cellular Immunotherapy.** At the 2019 American Society of Hematology (ASH) Annual Meeting in December, the Company presented preclinical data for FT538, the Company's off-the-shelf NK cell cancer immunotherapy for multiple myeloma. FT538 is derived from a clonal master iPSC line engineered with hnCD16 and IL-15RF, and edited for complete elimination of CD38 expression to mitigate anti-CD38 antibody-mediated fratricide. The Company intends to submit an IND application to the FDA for clinical investigation of FT538 in combination with anti-CD38 mAb therapy in the second quarter of 2020.
- **FT819 Master Engineered iPSC Bank Generated and Fully Characterized.** FT819 is the Company's first off-the-shelf, iPSC-derived CAR T-cell product candidate, and is derived from a clonal master engineered iPSC line engineered with a novel 1XX CAR targeting CD19 inserted into the T-cell receptor alpha constant (TRAC) locus, and edited for complete elimination of T-cell receptor (TCR) expression. At ASH, scientists from the Company and Memorial Sloan Kettering Cancer Center presented new *in vivo* preclinical data demonstrating that, in a xenograft model of disseminated lymphoblastic leukemia, FT819 enhanced tumor clearance and extended survival as compared to primary CAR19 T cells. The Company intends to submit an IND application to the FDA for clinical investigation of FT819 in the second quarter of 2020.

Fourth Quarter 2019 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of December 31, 2019 were $260.9 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 and to fully retire its debt facility.
- **Total Revenue:** Revenue was $2.8 million for the fourth quarter of 2019, compared to $1.7 million for the same period in 2018. Revenue for the fourth quarter of 2019 was derived from the Company's collaboration with Ono Pharmaceutical.
- **R&D Expenses:** Research and development expenses were $25.2 million for the fourth quarter of 2019, compared to $14.1 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 $6.7 million for the fourth quarter of 2019, compared to $4.3 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 75.7 million as of December 31, 2019 and 64.7 million as of December 31, 2018. Preferred shares outstanding as of December 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, Monday, March 2, 2020 at 5:00 p.m. ET to review financial and operating results for the quarter ended December 31, 2019. In order to participate in the conference call, please dial 877-303-6229 (domestic) or 631-291-4833 (international) and refer to conference ID 9879730. 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 300 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 (NCT03841110). The study is designed to assess the safety and tolerability 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 their disease progresses 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 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies. CD16 mediates antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells. ADCC is

dependent on NK cells maintaining stable and effective expression of CD16, which has been shown to undergo considerable down-regulation in cancer patients. In addition, CD16 occurs in two variants, 158V or 158F, that elicit high or low binding affinity, respectively, to 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. FT516 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 (NCT04023071). Additionally, the FDA has allowed investigation of FT516 in an open-label, multi-dose Phase 1 clinical trial in combination with monoclonal antibody therapy, including PDL1-, PD1-, EGFR- and HER2-targeting therapeutic antibodies, across a broad range of solid tumors.

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 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; and an IL-15 receptor fusion (IL-15RF) that promotes enhanced NK cell activity. In preclinical studies of FT596, the Company has demonstrated that dual activation of the CAR19 and hnCD16 targeting 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 humanized mouse model of lymphoma, FT596 in combination with the anti-CD20 monoclonal antibody rituximab showed enhanced killing of tumor cells *in vivo* as compared to rituximab alone. FT596 is being investigated in an open-label Phase 1 clinical trial as a monotherapy, and in combination with rituximab, for the treatment of advanced B-cell lymphoma and in combination with obinutuzumab for the treatment of chronic lymphocytic leukemia (NCT04245722).

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 patients 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 patient 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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration revenue	$ 2,802	$ 1,661	$ 10,680	$ 4,
Operating expenses:				
Research and development	25,209	14,095	87,770	56,
General and administrative	6,671	4,307	23,637	15,
Total operating expenses	31,880	18,402	111,407	71,
Loss from operations	(29,078)	(16,741)	(100,727)	(67,
Other income (expense):				
Interest income	1,314	1,144	4,330	2,
Interest expense	(538)	(430)	(1,752)	(1,
Total other income, net	776	714	2,578	
Net loss	$ (28,302)	$ (16,027)	$ (98,149)	$ (66,
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	(29)	12	24	
Comprehensive loss	$ (28,331)	$ (16,015)	$ (98,125)	$ (66,
Net loss per common share, basic and diluted	$ (0.37)	$ (0.25)	$ (1.44)	$ (1
Weighted–average common shares used to compute basic and diluted net loss per share	75,596,026	64,595,822	68,190,741	56,195,

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 99,814	$ 190,514
Short-term investments and related maturity receivables	121,613	10,493
Accounts receivable	—	500
Prepaid expenses and other current assets	5,662	3,689
Total current assets	227,089	205,196
Long-term investments	39,440	—
Operating lease right-of-use asset	22,752	—
Other long-term assets	12,993	7,836
Total assets	$ 302,274	$ 213,032
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 20,519	$ 15,131
Deferred revenue, current portion	2,787	7,588
CIRM award liability, current portion	2,808	2,106
Operating lease liability, current portion	1,692	—
Long-term debt, current portion	—	2,438
Total current liabilities	27,806	27,263
Deferred revenue, net of current portion	3,775	7,500
CIRM award liability, net of current portion	702	1,404
Operating lease liability, net of current portion	25,235	—
Long-term debt, net of current portion	—	12,446
Other long-term liabilities	—	3,950
Stockholders' equity	244,756	160,469
Total liabilities and stockholders' equity	$ 302,274	$ 213,032

Contact:
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