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 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))

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 5, 2019, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2018. 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 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: March 5, 2019

FATE THERAPEUTICS, INC.

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

Fate Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results and Highlights Operational Progress

First Patient Treated with FT500 Off-the-Shelf NK Cell Cancer Immunotherapy in Landmark Clinical Trial

Marks First-ever Human Administration of iPSC-derived Cell Therapy in the United States

$201 Million in Cash & Short-term Investments as of December 31, 2018

San Diego, CA – **March 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 fourth quarter and year ended December 31, 2018.

"We achieved an unprecedented milestone in treating the first patient with FT500, which is the first-ever administration of an iPSC-derived cell therapy to a patient in the U.S. In 2018, we made great strides toward our vision of using master iPSC lines to produce universal, off-the-shelf cell-based cancer immunotherapies that are available 'on demand' and deliver transformational change in patient outcomes," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "The year was also highlighted by strong clinical execution and encouraging patient data for our ongoing allogeneic cell therapy programs, ProTmune and FATE-NK100. Additionally, our industry-leading iPSC product platform delivered multiple highly differentiated, off-the-shelf NK cell and T-cell product candidates, which we expect to move into the clinic in 2019."

Clinical Programs

- **First-ever iPSC-derived Cell Product FT500 Administered to a Patient in the U.S.** In November 2018, the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application for FT500, a universal, off-the-shelf natural killer (NK) cell product candidate derived from a clonal master induced pluripotent stem cell (iPSC) line. The landmark clinical trial is intended to assess the safety and efficacy of multiple doses of FT500 over multiple dosing cycles for the treatment of advanced solid tumors as a monotherapy and as a combination with nivolumab, pembrolizumab or atezolizumab in patients that failed to respond to, or progressed on, checkpoint inhibitor therapy. The first subject was treated with FT500 in February 2019.
- **Anti-Tumor Activity of FATE-NK100 Observed Across Three Phase 1 Studies.** In November 2018, the Company reported initial dose-escalation clinical data of FATE-NK100 from fifteen subjects across three Phase 1 clinical trials for the treatment of relapsed / refractory acute myelogenous leukemia, recurrent ovarian cancer and advanced solid tumors. As of an October 22, 2018 data cutoff, no FATE-NK100-related dose limiting toxicities were reported, and anti-tumor activity was

observed with a single dose of FATE-NK100 in seven of the fifteen subjects. Three of these seven subjects were subsequently treated with a second dose of FATE-NK100, which was well-tolerated and showed persistence. All three of these subjects achieved durable disease control for at least three months, providing initial proof-of-concept for multi-dose administration of donor NK cell therapy.

- **Presented One-Year Follow-up Data from Phase 1 PROTECT Study of ProTmune™.** At the 2018 American Society of Hematology (ASH) Annual Meeting, the Company released new clinical data from the seven subjects receiving ProTmune for the treatment of hematologic malignancies in the Phase 1 stage of the PROTECT study. As of a November 26, 2018 data cutoff with a median time on study of 516 days [range 151-616], there were no ProTmune-related SAEs reported by investigators, no events of graft failure and no events of leukemia relapse, and five of seven subjects remained alive and leukemia-free (71%). Additionally, three of seven subjects (43%) successfully met a novel composite endpoint of freedom from moderate-to-severe chronic graft-versus-host disease (GvHD), leukemia relapse and death at one year, which endpoint is intended to measure the overall effectiveness of allogeneic HCT. The Company expects to complete enrollment of the randomized, controlled and double-blind Phase 2 PROTECT study in 2019, and that data on the primary and secondary endpoints will be available in 2020.

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 January 2019, the Company submitted an IND application to the FDA 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. CD16 mediates antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells. Numerous clinical studies with FDA-approved tumor-targeting antibodies have demonstrated that patients with the CD16 high-affinity variant (158V) have improved clinical outcomes. The Company announced in February 2019 that the FDA allowed its FT516 IND application for the treatment of relapsed / refractory hematologic malignancies including in combination with certain FDA-approved monoclonal antibody therapies. FT516 is the first-ever cell product derived from a genetically engineered pluripotent stem cell cleared for clinical testing worldwide.
- **Presented FT596 Preclinical Data of Dual Antigen-Specific Targeting.** 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 hnCD16 Fc receptor for augmented ADCC and a novel IL-15 receptor fusion for cytokine-independent persistence. A presentation at ASH by scientists from the Company and the University of California – San Diego highlighted new *in vivo* data demonstrating that FT596 displays enhanced persistence and promotes long-term survival in a B-cell leukemia xenograft model. Moreover, as proof-of-concept for dual antigen-specific targeting and the mitigation of antigen escape, FT596 in combination with rituximab completely eliminated CD19+ and CD19- tumor cells in a co-culture cellular cytotoxicity assay. The Company expects to submit an IND application to the FDA in mid-2019 for clinical investigation of FT596.

- **Presented *In Vivo* Preclinical Data from Off-the-Shelf, iPSC-derived CAR T-cell Program.** A presentation at ASH by scientists from the Company and Memorial Sloan Kettering Cancer Center (MSK) showcased new *in vivo* data demonstrating that the control of tumor progression with FT819, the Company's off-the-shelf, TCR-less, CD19-targeted CAR T-cell product candidate manufactured from a clonal master iPSC, is comparable to that with peripheral blood CAR T cells in a preclinical mouse model of acute lymphoblastic leukemia. The clonal master iPSC line includes the targeted integration of a novel 1XX CAR into the T-cell receptor α constant (TRAC) locus, which is intended to regulate CAR expression for enhanced safety and efficacy and completely eliminate T-cell receptor (TCR) expression to mitigate GvHD. FT819 is being co-developed under a collaboration with MSK led by Dr. Michel Sadelain.

Corporate Highlights

- **In-licensed Novel Humanized anti-BCMA CAR Constructs.** In December 2018, the Company announced that it had entered into an agreement with the Max Delbrück Center (MDC) for exclusive access to a broad intellectual property portfolio of humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen (BCMA). In a recent publication entitled "*CAR T Cells with Enhanced Sensitivity to B Cell Maturation Antigen for the Targeting of B Cell Non-Hodgkin's Lymphoma and Multiple Myeloma"* (*doi:10.1016/j.ymthe.2018.06.012*), scientists from MDC demonstrated that anti-BCMA CAR T cells equipped with its unique humanized extracellular antigen-binding domains have both greater selectivity and sensitivity in recognizing, and more robust killing of, target B cells *in vitro* as compared to other anti-BCMA antigen-binding domains.
- **Initiated Build-out of In-house GMP Manufacturing.** In January 2019, the Company expanded its corporate headquarters in San Diego to include state-of-the art GMP manufacturing facilities for the clinical supply of its off-the-shelf, iPSC-derived cell product candidates. The modular design is customized to support the mass production of multiple product candidates in parallel. The Company expects to initiate in-house GMP manufacture of its off-the-shelf, iPSC-derived cell product candidates in the second half of 2019.

Fourth Quarter 2018 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of December 31, 2018 were $201.0 million, compared to $100.9 million as of December 31, 2017. The increase was primarily driven by $134.9 million in net cash proceeds received by the Company from its September 2018 public offering of common stock. These proceeds were offset by the Company's use of cash to fund operating activities.
- **Total Revenue:** Revenue was $1.7 million for the fourth quarter of 2018, compared to $1.0 million for the same period in 2017. Revenue was derived from the Company's collaborations with Ono Pharmaceutical and Juno Therapeutics.
- **R&D Expenses:** Research and development expenses were $14.1 million for the fourth quarter of 2018, compared to $9.9 million for the same period in 2017. 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 $4.3 million for the fourth quarter of 2018, compared to $3.4 million for the same period in 2017. The increase in G&A expenses was primarily attributable to an increase in employee compensation, including share-based compensation, and in professional fees.
- **Shares Outstanding:** Common shares outstanding were 64.7 million as of December 31, 2018 and 52.6 million as of December 31, 2017. Preferred shares outstanding as of December 31, 2018 and December 31, 2017 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, March 5, 2019 at 5:00 p.m. ET to review financial and operating results for the quarter ended December 31, 2018. In order to participate in the conference call, please dial 877-303-6235 (domestic) or 631-291-4837 (international) and refer to conference ID 3374407. 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 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-NK100
FATE-NK100 is an investigational, first-in-class, allogeneic donor-derived natural killer (NK) cell cancer immunotherapy comprised of adaptive memory NK cells, a highly specialized and functionally distinct subset of activated NK cells expressing the maturation marker CD57. Higher frequencies of $CD57^+$ NK cells in the peripheral blood or tumor microenvironment in cancer patients have been linked to better clinical outcomes. In August 2017, non-clinical data describing the unique properties and anti-tumor activity of FATE-NK100 were published by *Cancer Research* (doi:10.1158/0008-5472.CAN-17-0799), a peer-reviewed journal of the American Association of Cancer Research. Three clinical trials of FATE-NK100 are currently being conducted: VOYAGE for the treatment of refractory or relapsed acute myelogenous leukemia; APOLLO for the treatment of recurrent ovarian cancer; and DIMENSION for the treatment of advanced solid tumors, including in combination with monoclonal antibody therapy.

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. FT500 is being investigated in an open-label, repeat-dose Phase 1 clinical trial for the treatment of advanced solid tumors in up to 64 subjects, both as a monotherapy and in combination with FDA-approved checkpoint inhibitor therapy. Despite the favorable response rates observed with checkpoint inhibitor therapy, the majority of patients do not respond and many responders relapse. 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.

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 addressing the 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 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 off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline is comprised of FATE-NK100, a donor-derived natural killer (NK) cell cancer immunotherapy that is currently being evaluated in three Phase 1 clinical trials, as well as iPSC-derived NK cell and T-cell immunotherapies, with a focus on developing next-generation cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens. 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 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 December 31,		Years Ended December 31,	
	2018	**2017**	**2018**	**2017**
Collaboration revenue	$ 1,661	$ 1,027	$ 4,740	$ 4,106
Operating expenses:				
Research and development	14,095	9,887	56,024	34,358
General and administrative	4,307	3,384	15,808	11,873
Total operating expenses	18,402	13,271	71,832	46,231
Loss from operations	(16,741)	(12,244)	(67,092)	(42,125)
Other income (expense):				
Interest income	1,144	159	2,190	559
Interest expense	(430)	(412)	(1,696)	(1,268)
Loss on extinguishment of debt	—	—	—	(118)
Total other income (expense), net	714	(253)	494	(827)
Net loss	$ (16,027)	$ (12,497)	$ (66,598)	$ (42,952)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for- sale securities, net	12	10	1	(2)
Comprehensive loss	$ (16,015)	$ (12,487)	$ (66,597)	$ (42,954)
Net loss per common share, basic and diluted	$ (0.25)	$ (0.29)	$ (1.19)	$ (1.02)
Weighted–average common shares used to compute basic and diluted net loss per share	64,595,822	43,685,961	56,195,650	41,982,167

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 190,514	$ 88,952
Accounts receivable	500	—
Short-term investments and related maturity receivables	10,493	11,997
Prepaid expenses and other current assets	3,689	1,647
Total current assets	205,196	102,596
Long-term assets	7,836	2,696
Total assets	$ 213,032	$ 105,292
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,131	$ 8,932
CIRM award liability, current portion	2,106	—
Long-term debt, current portion	2,438	—
Current portion of deferred revenue	7,588	2,105
Other current liabilities	—	12
Total current liabilities	27,263	11,049
Long-term debt, net of current portion	12,446	14,808
CIRM award liability, net of current portion	1,404	—
Deferred revenue	7,500	724
Other long-term liabilities	3,950	1,522
Stockholders' equity	160,469	77,189
Total liabilities and stockholders' equity	$ 213,032	$ 105,292

Contact:
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