

**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, 2018

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36076
(Commission
File Number)

65-1311552
(I.R.S. Employer
Identification No.)

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, 2018, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2017. A copy of the press release is attached as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”) or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 5, 2018

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, 2018

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



Fate Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results and Highlights Operational Progress

Initial Clinical Data of FATE-NK100 in Relapsed / Refractory AML Show Rapid Reduction of Leukemic Blasts in the Bone Marrow

All Subjects in PROTECT Phase 1 Study of ProTmune Achieve Day 100 Relapse-free Survival

Clinical-scale Production of FT500 Off-the-Shelf NK Cell Cancer Immunotherapy Initiated in Support of Landmark IND Filing

Breakthrough Generation of Universal CAR T cells from Clonal Master iPSC Line Achieved under MSK Collaboration

Preclinical Data of FT819 Off-the-Shelf CAR19 T-cell Product Candidate Demonstrate Target-specific Anti-tumor Activity

San Diego, CA– March 5, 2018 – 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, 2017.

“Initial clinical observations from the investigation of our first-in-class product candidates have established Fate Therapeutics as a leading innovator in the development of next-generation cellular immunotherapies. We look forward to sharing additional clinical data from three ongoing studies of FATE-NK100 and the PROTECT Phase 1 study of ProTmune at upcoming scientific conferences throughout 2018,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “In addition, we are now poised to advance FT500, our first iPSC-derived NK cell cancer immunotherapy, to a landmark IND filing in the first half of 2018. We believe our proprietary iPSC product platform, which we are applying to consistently produce large quantities of uniform, well-characterized NK cells and T cells from clonal master iPSC lines, can transform cell therapy from a single-dose, patient-restricted process to a multi-dose, off-the-shelf product paradigm. Upon clearance of this first IND from our iPSC product platform, we are well positioned to rapidly advance multiple off-the-shelf cancer immunotherapies, including our engineered NK cell and universal CAR T-cell products, into clinical development.”

Clinical Programs – Highlights & Updates

- **Anti-Leukemia Activity of FATE-NK100 Observed in VOYAGE Study** In November 2017, initial clinical data of FATE-NK100, a first-in-class adaptive memory natural killer (NK) cell product, from
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the ongoing VOYAGE study for the treatment of refractory or relapsed acute myelogenous leukemia (AML) were presented at the Society for Immunotherapy of Cancer Annual Meeting. At two weeks following a single intravenous infusion of FATE-NK100, the subject in the first dose cohort showed nearly a 50% reduction in leukemic blasts and the subject in the second dose cohort achieved a morphologic leukemia-free state based on bone marrow biopsy. No dose limiting toxicities were reported.

- **Advanced FATE-NK100 through First Two Dose Cohorts of APOLLO Study** In December 2017, the APOLLO study of FATE-NK100 was initiated for the treatment of women with ovarian cancer that is resistant to, or recurrent on, platinum-based treatment. FATE-NK100 has advanced through the first two dose cohorts with no reports of dose limiting toxicities. The Company expects to release initial clinical data from the ongoing APOLLO study at the 3rd Innate Killer Summit (March 27-29, San Diego).
- **Reported Day 100 Clinical Data from Phase 1 Stage of PROTECT Study of ProTmune™** In December 2017, initial clinical data of ProTmune, a next-generation hematopoietic cell graft, were presented at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition. During the first 100 days following hematopoietic cell transplantation (HCT), all seven subjects receiving ProTmune in the Phase 1 stage of the PROTECT study for the treatment of hematologic malignancies remained alive and relapse-free. Three subjects experienced acute graft-versus-host disease (GvHD) during the first 100 days following HCT, all of whom responded to standard-of-care steroid treatment. There were no ProTmune-related serious adverse events reported by investigators.

Preclinical Programs – Highlights & Updates

- **Initiated IND-enabling Manufacture of FT500 iPSC-derived NK Cell Cancer Immunotherapy** Clinical-scale production of FT500, a first-of-kind, off-the-shelf NK cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line, commenced at Molecular and Cellular Therapeutics, a state-of-the-art, FDA-registered Good Manufacturing Practice (GMP) facility. The Company is currently preparing an Investigational New Drug (IND) application for FT500 for submission to the U.S. Food and Drug Administration (FDA) in the first half of 2018. The Company plans to clinically investigate multiple dosing cycles of FT500 in combination with FDA-approved checkpoint inhibitor therapy for the treatment of advanced solid tumors.
 - **Presented Preclinical Data for FT819 iPSC-derived CAR19 T-Cell Cancer Immunotherapy** In December 2017, scientists from the laboratories of Michel Sadelain, M.D., Ph.D., Director, Center for Cell Engineering, Memorial Sloan Kettering Cancer Center, and Fate Therapeutics presented at ASH the generation of iPSC-derived, anti-CD19 chimeric antigen receptor (CAR)-targeted, TCR-null CD8 $\alpha\beta$ ⁺ T cells. The universal T cells were derived from a single iPSC engineered to completely eliminate T-cell receptor (TCR) expression and to insert a CAR targeting CD19 into the T-cell receptor α constant (TRAC) locus. The groundbreaking development enables the renewable production of large quantities of CAR T cells, from a clonal master iPSC line, that are uniformly engineered and are not patient-restricted. In preclinical studies, the collaborators demonstrated that the universal CAR T cells displayed target-specificity and potent anti-tumor activity. Fate
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Therapeutics is currently advancing FT819, an off-the-shelf CAR19 T-cell product candidate derived from a clonal master iPSC line engineered with complete TCR elimination and TRAC-regulated CAR expression.

- **Launched Collaboration with UCSD for Development of iPSC-derived CAR NK Cell Cancer Immunotherapies** The multi-year research collaboration with the University of California, San Diego (UCSD) is being led by Dan S. Kaufman, M.D., Ph.D., Professor of Medicine in the Division of Regenerative Medicine and Director of Cell Therapy. Dr. Kaufman and Fate Therapeutics have developed a novel CAR construct specifically designed to enhance NK cell activation and persistence that is comprised of a NKG2D transmembrane domain, a 2B4 co-stimulatory domain and a CD3ζ signaling domain. Preclinical data presented at ASH demonstrated that a single dose of these iPSC-derived CAR NK cells markedly inhibited tumor growth and significantly enhanced survival as compared to iPSC-derived CAR NK cells containing a construct commonly used in T cells.

Fourth Quarter 2017 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of December 31, 2017 were \$100.9 million compared to \$92.1 million as of December 31, 2016. The increase was primarily driven by \$43.2 million in net cash proceeds received by the Company from its December 2017 public offering of common stock and \$7.5 million in net cash proceeds received by the Company in July 2017 in connection with the amendment of its loan agreement with Silicon Valley Bank. These proceeds were offset by the Company's use of cash to fund operating activities and to service principal and interest obligations under its loan agreement with Silicon Valley Bank.
 - **Total Revenue:** Revenue was \$1.0 million for the fourth quarter of 2017 as well as for the comparable period in 2016. All revenue was derived from the Company's research collaboration and license agreement with Juno Therapeutics.
 - **Total Operating Expenses:** Total operating expenses were \$13.3 million for the fourth quarter of 2017 compared to \$8.7 million for the comparable period in 2016. Operating expenses for the fourth quarter of 2017 included \$0.9 million of stock compensation expense compared to \$0.8 million for the comparable period in 2016.
 - **R&D Expenses:** Research and development expenses were \$9.9 million for the fourth quarter of 2017 compared to \$6.2 million for the comparable period in 2016. The increase in R&D expenses was attributable to an increase in third-party service provider fees for the manufacture and clinical development of ProTmune and FATE-NK100 and for FT500 IND-enabling activities, as well as an increase in equipment and materials associated with the advancement of the Company's iPSC-derived cancer immunotherapy programs, employee compensation and benefits expense, and facilities costs associated with the expansion of the Company's laboratory space.
 - **G&A Expenses:** General and administrative expenses were \$3.4 million for the fourth quarter of 2017 compared to \$2.5 million for the comparable period in 2016. The increase in G&A expenses was attributable to an increase in intellectual property-related expenses and licensing costs.
 - **Shares Outstanding:** Common shares outstanding were 52.6 million as of December 31, 2017 and 41.4 million as of December 31, 2016. Preferred shares outstanding as of December 31, 2017 and
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December 31, 2016 were 2.82 million, each of which is convertible into five shares of common stock. All preferred shares outstanding are from the Company's sale and issuance of non-voting Class A convertible preferred stock to Redmile Group, LLC in November 2016.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Monday, March 5, 2018 at 5:00 p.m. ET to review financial and operating results for the quarter ended December 31, 2017. In order to participate in the conference call, please dial 877-303-6235 (domestic) or 631-291-4837 (international) and refer to conference ID 7589759. 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-NK100

FATE-NK100 is a 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 ProTmune™

ProTmune™ is an investigational next-generation hematopoietic cell graft for the prevention of acute graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic cell transplantation (HCT). 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-blinded Phase 2 clinical trial in adult subjects with hematologic malignancies undergoing matched unrelated donor HCT.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables large-scale generation 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 consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in an off-the-shelf manner. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 90 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 therapies using its proprietary induced pluripotent stem cell (iPSC) product platform. This platform uniquely enables the single-cell selection of a precisely engineered iPSC clone and the subsequent creation and maintenance of 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 consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in an off-the-shelf manner. 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 augmented cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-specific antigens. The Company's immuno-regulatory pipeline includes ProTmune™, a next-generation 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 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 its manufacture and clinical investigation of ProTmune™ and FATE-NK100 and its manufacture, preclinical development and clinical investigation of its iPSC-derived product candidates, the Company's receipt of data from its clinical trials and preclinical studies, the Company's development and regulatory strategy, including the therapeutic and market potential, for its product candidates, and the Company's financial condition and projected cash expenditures. 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 its product candidates, including preclinical studies

and clinical trials of ProTmune and FATE-NK100, will not be observed in ongoing or future studies involving these product candidates, the risk of a delay in the enrollment or evaluation 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		Years Ended	
	December 31,		December 31,	
	2017	2016	2017	2016
Collaboration revenue	\$ 1,027	\$ 1,027	\$ 4,106	\$ 4,402
Operating expenses:				
Research and development	9,887	6,230	34,358	26,452
General and administrative	3,384	2,451	11,873	9,913
Total operating expenses	13,271	8,681	46,231	36,365
Loss from operations	(12,244)	(7,654)	(42,125)	(31,963)
Other income (expense):				
Interest income	159	43	559	138
Interest expense	(412)	(329)	(1,268)	(1,637)
Loss on extinguishment of debt	—	—	(118)	—
Total other expense, net	(253)	(286)	(827)	(1,499)
Net loss	\$ (12,497)	\$ (7,940)	\$ (42,952)	\$ (33,462)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	10	(4)	(2)	(1)
Comprehensive loss	\$ (12,487)	\$ (7,944)	\$ (42,954)	\$ (33,463)
Net loss per common share, basic and diluted	\$ (0.29)	\$ (0.21)	\$ (1.02)	\$ (1.05)
Weighted-average common shares used to compute basic and diluted net loss per share	43,685,961	37,216,488	41,982,167	31,754,140

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,952	\$ 88,609
Short-term investments and related maturity receivables	11,997	3,503
Prepaid expenses and other current assets	1,647	1,211
Total current assets	102,596	93,323
Long-term assets	2,696	1,725
Total assets	\$ 105,292	\$ 95,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,932	\$ 4,891
Long-term debt, current portion	—	8,187
Current portion of deferred revenue	2,105	2,105
Other current liabilities	12	4
Total current liabilities	11,049	15,187
Long-term debt, net of current portion	14,808	2,501
Deferred revenue	724	2,829
Other long-term liabilities	1,522	1,377
Stockholders' equity	77,189	73,154
Total liabilities and stockholders' equity	\$ 105,292	\$ 95,048

Contact:

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