

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 10, 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 May 10, 2018, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 10, 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: May 10, 2018

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



Fate Therapeutics Reports First Quarter 2018 Financial Results and Highlights Operational Progress

No Cancer Relapse Reported in Phase 1 PROTECT Study of ProTmune

Anti-tumor Activity with No Dose-limiting Toxicities Observed in Initial Phase 1 Dose Escalation of FATE-NK100 in Advanced Solid and Liquid Tumors

IND for Off-the-Shelf NK Cell Product FT500 Remains on Track for 2Q18 Submission

Off-the-Shelf Dual-targeted CAR T-cell Product Demonstrates CD19 and CD20 Anti-Tumor Activity in Preclinical Studies of Antigen Escape

San Diego, CA– May 10, 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 first quarter ended March 31, 2018.

“We have generated a strong package of preclinical safety, efficacy and manufacturing data for FT500, and expect to submit an IND application for this first-of-kind NK cell product in the second quarter of 2018. We look forward to continuing our productive interactions with the FDA to pioneer the use of clonal master iPSC lines for the renewable production and clinical use of universal, off-the-shelf cellular immunotherapies for cancer,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “In addition, we are encouraged by the initial clinical data emerging from our two donor-derived cell therapy programs. We have observed safety, persistence and anti-tumor activity with NK100 in initial Phase 1 dose escalation against solid and liquid tumors. Additionally, no events of cancer relapse have been reported in our Phase 1 PROTECT study of ProTmune, and new immune reconstitution data from these subjects support the potential of ProTmune to fight against infections and residual disease.”

Clinical Programs – Highlights & Updates

- **Reported New ProTmune™ Clinical Data Showing No Events of Cancer Relapse**In March, the Company presented additional Phase 1 PROTECT data from seven subjects administered ProTmune, the Company’s next-generation hematopoietic cell graft for patients with hematologic malignancies. As of a February 26, 2018 data cut-off, with a median time on study of 228 days, no serious adverse events related to ProTmune and no events of cancer relapse had been reported by investigators. The Company also presented immune reconstitution data, which indicate that the T- and NK cell compartments of ProTmune are functional and capable of fighting against infections
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and cancer. The randomized, controlled and double-blinded Phase 2 PROTECT study is currently open for enrollment at 15 U.S. centers.

- **Advancing FATE-NK100 in Multiple Phase 1 Studies**In February, the first subject was administered NK100, the Company's first-in-class, donor-derived adaptive memory natural killer (NK) cell cancer immunotherapy, in the DIMENSION study. This ongoing Phase 1 clinical trial is assessing the safety and efficacy of NK100 when administered as a monotherapy and in combination with trastuzumab or cetuximab, two FDA-approved monoclonal antibodies that are widely used today to treat various solid tumor malignancies. Additionally, initial clinical data from the first two subjects administered NK100 in the ongoing Phase 1 APOLLO study for recurrent ovarian cancer were presented at the Innate Killer Summit in March and showed no dose-limiting toxicities. The Day 28 response evaluation for Subject 2 showed stable disease with evidence of tumor reduction.

Universal Off-the-Shelf Cancer Immunotherapy Preclinical Programs – Highlights & Updates

- **Completed Key Activities to Support FT500 IND Submission**The Company remains on track to submit in the second quarter of 2018 an Investigational New Drug (IND) application for FT500, a universal, off-the-shelf NK cell product manufactured from a clonal master induced pluripotent stem cell (iPSC) line. A preclinical *in vivo* GLP toxicity and tumorigenicity study in animals demonstrated that FT500 was well tolerated. There were no mortality events in any FT500-treated cohorts and no adverse clinical observations related to FT500. Additionally, FT500 produced from multiple clinical-scale manufacturing runs met pre-established specifications for identity, purity and potency as set forth in the Company's pre-IND meeting with the FDA. The Company plans to clinically investigate FT500 in combination with FDA-approved checkpoint inhibitors as a rescue therapy.
 - **Secured \$4M from CIRM to Advance FT516 into a First-in-Human Clinical Trial**The award from the California Institute for Regenerative Medicine (CIRM) is being used to support ongoing IND-enabling activities. FT516 is a universal, off-the-shelf NK cell product manufactured from a clonal master iPSC line engineered to uniformly express a high-affinity, non-cleavable CD16 Fc receptor. Since CD16 is able to bind the Fc region of tumor-targeted antibodies, FT516 can be combined with FDA-approved monoclonal antibody therapies to target a broad spectrum of tumor-associated antigens. The Company has shown in preclinical studies that FT516 exhibits potent and persistent anti-tumor activity *in vitro* and *in vivo* against multiple tumor types, including in combination with monoclonal antibody therapies that target CD20, HER2 and EGFR.
 - **Presented Dual-targeted Anti-tumor Activity of FT819 for Antigen Escape**The Company presented breakthrough preclinical data demonstrating the dual-targeted anti-tumor activity of FT819, a universal, off-the-shelf CAR19 T-cell product, at the American Association for Cancer Research Annual Meeting in April. FT819 exhibited a target-specific T-cell response *in vitro* when challenged with CD19-positive tumor cells and displayed robust production of effector cytokines and cytolytic proteins. In addition, FT819 elicited antibody-dependent cell-mediated cytotoxicity *in vitro* against CD19-negative, CD20-positive tumor cells when combined with rituximab, a monoclonal antibody targeting CD20. The Company is developing FT819, which is derived from a clonal master iPSC line engineered to completely eliminate the T-cell receptor, insert a chimeric antigen receptor (CAR) targeting CD19 into the T-cell receptor (TRAC) locus and express CD16 to
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mitigate antigen escape, under its exclusive iPSC-derived T-cell collaboration with Memorial Sloan Kettering Cancer Center led by Michel Sadelain, M.D., Ph.D., Director, Center for Cell Engineering.

First Quarter 2018 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of March 31, 2018 were \$88.6 million compared to \$100.9 million as of December 31, 2017. The decrease was primarily driven by the Company's use of cash to fund operating activities.
- **Total Revenue:** Revenue was \$1.0 million for the first quarter of 2018 as well as for the same period in 2017. All revenue was derived from the Company's research collaboration and license agreement with Juno Therapeutics.
- **R&D Expenses:** Research and development expenses were \$11.5 million for the first quarter of 2018, compared to \$8.0 million for the same period in 2017. The increase in R&D expenses was primarily attributable to an increase in third-party service provider fees related to the clinical development and manufacture of ProTmune and FATE-NK100 and to IND-enabling activities for FT500, as well as an increase in equipment and materials associated with the preclinical development of the Company's iPSC-derived cancer immunotherapy programs and in employee compensation associated with growth in headcount.
- **G&A Expenses:** General and administrative expenses were \$3.6 million for the first quarter of 2018, compared to \$3.0 million for the same period in 2017. The increase in G&A expenses was primarily attributable to an increase in stock-based compensation expense and in intellectual property costs.
- **Shares Outstanding:** Common shares outstanding were 52.9 million as of March 31, 2018 and 52.6 million as of December 31, 2017. Preferred shares outstanding as of March 31, 2018 and December 31, 2017 were 2.8 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, Thursday, May 10th, 2018 at 5:00 p.m. ET to review financial and operating results for the quarter ended March 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 5592629. 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 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 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 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 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. 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 timing for 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	
	March 31,	
	2018	2017
Collaboration revenue	\$ 1,026	\$ 1,027
Operating expenses:		
Research and development	11,476	7,966
General and administrative	3,604	3,032
Total operating expenses	15,080	10,998
Loss from operations	(14,054)	(9,971)
Other income (expense):		
Interest income	331	111
Interest expense	(412)	(266)
Total other expense, net	(81)	(155)
Net loss	\$ (14,135)	\$ (10,126)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net	(10)	(33)
Comprehensive loss	\$ (14,145)	\$ (10,159)
Net loss per common share, basic and diluted	\$ (0.27)	\$ (0.24)
Weighted-average common shares used to compute basic and diluted net loss per share	52,763,306	41,388,329

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>March 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,912	\$ 88,952
Accounts receivable	500	—
Short-term investments and related maturity receivables	55,722	11,997
Prepaid expenses and other current assets	1,491	1,647
Total current assets	<u>90,625</u>	<u>102,596</u>
Long-term assets	2,795	2,696
Total assets	<u>\$ 93,420</u>	<u>\$ 105,292</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,600	\$ 8,932
Long-term debt, current portion	758	—
Current portion of deferred revenue	2,105	2,105
Other current liabilities	125	12
Total current liabilities	<u>12,588</u>	<u>11,049</u>
Long-term debt, net of current portion	14,069	14,808
Deferred revenue	198	724
Other long-term liabilities	1,570	1,522
Stockholders' equity	64,995	77,189
Total liabilities and stockholders' equity	<u>\$ 93,420</u>	<u>\$ 105,292</u>

Contact:

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