

FATE THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 05/15/17 for the Period Ending 05/15/17

Address	3535 GENERAL ATOMICS COURT SUITE 200 SAN DIEGO, CA 92121
Telephone	858.875.1803
CIK	0001434316
Symbol	FATE
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 15, 2017

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 15, 2017, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 May 15, 2017

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 15, 2017

FATE THERAPEUTICS, INC.

By :/s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.
99.1

Description
Press release dated May 15, 2017



Fate Therapeutics Reports First Quarter 2017 Financial Results

ProTmune™ PROTECT Safety Data Expected in Mid-2017

Launched First-in-Human Clinical Trial of FATE-NK100 for Acute Myelogenous Leukemia

IND Cleared by FDA for FATE-NK100 with Monoclonal Antibody Therapy in Advanced Solid Tumors

Conducted Formal Regulatory Meetings with FDA and MHRA for Engineered iPSC-derived NK Cell Cancer Immunotherapy

San Diego, CA – May 15, 2017 – 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 quarter ended March 31, 2017.

“This has been an exciting quarter for us as we have successfully launched our multi-pronged clinical development strategy for FATE-NK100 across both hematologic and solid tumor malignancies. We also continue to be encouraged by investigator enthusiasm for ProTmune and look forward to sharing key clinical data in mid-2017 from the safety stage of our PROTECT study,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “Additionally, we are very pleased with the constructive feedback we received from regulatory authorities in both the United States and the United Kingdom regarding our specific manufacturing and development plans for our first-of-kind cell products derived from master pluripotent cell lines. These formal meetings confirmed our alignment with key regulatory agencies in bringing our off-the-shelf iPSC-derived cell products into human clinical trials.”

Recent Highlights & Program Updates

- **Launched First-in-Human Clinical Trial of FATE-NK100.** An investigator-initiated clinical trial of FATE-NK100, the Company’s first-in-class adaptive memory natural killer (NK) cell product candidate, was opened for patient enrollment at the Masonic Cancer Center, University of Minnesota (UMN) for the treatment of refractory or relapsed acute myelogenous leukemia. The VOYAGE study is utilizing accelerated dose-escalation to evaluate the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100. The anti-tumor activity of FATE-NK100, including rates of complete response, clearance of minimal residual disease, disease-free survival and overall survival, will also be assessed.
 - **Secured FDA Clearance of IND for FATE-NK100 in Advanced Solid Tumors.** In May 2017, the U.S. Food and Drug Administration (FDA) cleared the Company’s investigational new drug (IND)
-

application for the clinical investigation of FATE-NK100 , including in combination with monoclonal antibody therapy, in subjects with advanced solid tumor malignancies. The Company plans to enroll subjects in the DIMENSION s study concurrently across three FATE-NK100 treatment arms: as monotherapy for solid tumor malignancies, including small cell lung cancer and hepatocellular carcinoma; in combination with trastuzumab for advanced HER2+ cancers, including breast and gastric cancers; and in combination with cetuximab for advanced EGFR1+ cancers, including colorectal and head and neck cancers. A accelerated dose - escalation will be utilized to evaluate the safety and anti-tumor activity of FATE NK100 in an outpatient setting.

- **Conducted Formal Regulatory Engagements with FDA and MHRA for hnCD16-iNK Cell Product Candidate.** Fate Therapeutics held a Pre-IND meeting with the FDA and a Scientific Advice meeting with the UK Medicines and Healthcare products Regulatory Agency (MHRA) in March and April 2017, respectively, to support the clinical translation of its induced pluripotent stem cell (iPSC)-derived NK cell products. These formal meetings reviewed the Company's preclinical development, proposed manufacturing plans and clinical trial design for its first-of-kind NK cell product candidate, an off-the-shelf targeted cancer immunotherapy derived from an engineered iPSC line. Based on these interactions, the Company expects to file applications with both regulatory authorities within the next twelve months to conduct a first-in-human clinical trial for the treatment of cancer. In February 2017, Fate Therapeutics and UMN expanded their collaboration to initiate clinical translation of the Company's iPSC-derived NK cell products, including its off-the-shelf targeted hnCD16-iNK cell product candidate derived from a master iPSC line engineered to express a proprietary high-affinity, non-cleavable CD16 receptor (hnCD16).
- **Granted Foundational iPSC Manufacturing Patent.** In March 2017, the U.S. Patent and Trademark Office issued U.S. Patent No. 9,593,311 which protects cellular compositions comprising iPSCs and a WNT pathway activator, such as a GSK3 inhibitor. This latest issuance, which expires in 2029, continues to extend the Company's dominant U.S. patent position covering OCT4-based cell reprogramming, including gene expression vectors and cell compositions necessary for generating iPSCs. The newly-patented compositions are critical for selecting and expanding iPSC clones and for maintaining clonal populations in a state of pluripotency, both of which are required to create master pluripotent cell lines for the manufacture of homogeneous cell products. The patent, which is owned by the Whitehead Institute for Biomedical Research and licensed exclusively to the Company for all therapeutic purposes, adds to the Company's significant iPSC intellectual property portfolio of over 90 issued patents and 100 pending patent applications.

First Quarter 2017 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of March 31, 2017 were \$82.3 million compared to \$92.1 million as of December 31, 2016. The decrease was primarily driven 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 first quarter of 2017 compared to \$1.3 million 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 \$11.0 million for the first quarter of 2017 compared to \$9.2 million for the comparable period in 2016. Operating expenses for the first 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 \$8.0 million for the first quarter of 2017 compared to \$6.6 million for the comparable period in 2016. The increase in R&D expenses was primarily related to an increase in third-party service provider fees to support the clinical development of ProTmune and FATE-NK100 and the preclinical advancement of the Company's off-the-shelf iPSC-derived cellular immunotherapy programs.
- **G&A Expenses:** General and administrative expenses were \$3.0 million for the first quarter of 2017 compared to \$2.6 million for the comparable period in 2016. The increase in G&A expenses was primarily related to an increase in intellectual property-related expenses.
- **Shares Outstanding:** Common shares outstanding as of March 31, 2017 and December 31, 2016 were 41.4 million. Preferred shares outstanding as of March 31, 2017 and December 31, 2016 were 2.82 million, each of which is convertible into five shares of common stock. All preferred shares outstanding relate to the Company's sale and issuance of 2.82 million shares 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, May 15, 2017 at 5:00 p.m. ET to review financial and operating results for the quarter ended March 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 18632775. 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, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cells, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. 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 the Company's product candidates, clinical studies, research and development programs, the Company's progress and plans for its clinical investigation of ProTmune™ and of FATE-NK100, the Company's expected product development and regulatory strategy for its iPSC-derived product candidates, the scope of the Company's intellectual property, and the Company's 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, including preclinical studies of ProTmune and the Company's other product candidates, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay preclinical or clinical development activities for any of its existing or future product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities and requirements for regulatory approval, difficulties or delays in patient enrollment in current and planned clinical trials, 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 our 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 the Company's 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)

	Three Months Ended	
	March 31,	
	2017	2016
	(unaudited)	
Collaboration revenue	\$ 1,027	\$ 1,322
Operating expenses:		
Research and development	7,966	6,636
General and administrative	3,032	2,602
Total operating expenses	10,998	9,238
Loss from operations	(9,971)	(7,916)
Other income (expense):		
Interest income	111	27
Interest expense	(266)	(488)
Total other expense, net	(155)	(461)
Net loss	\$ (10,126)	\$ (8,377)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities, net	(33)	14
Comprehensive loss	\$ (10,159)	\$ (8,363)
Net loss per common share, basic and diluted	\$ (0.24)	\$ (0.29)
Weighted-average common shares used to compute basic and diluted net loss per share	41,388,329	28,777,790

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 40,608	\$ 88,609
Short-term investments	41,692	3,503
Prepaid expenses and other current assets	1,137	1,211
Total current assets	83,437	93,323
Long-term assets	1,892	1,725
Total assets	\$ 85,329	\$ 95,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,169	\$ 4,891
Long-term debt, current portion	7,620	8,187
Current portion of deferred revenue	2,105	2,105
Other current liabilities	3	4
Total current liabilities	16,897	15,187
Long-term debt, net of current portion	1,081	2,501
Deferred revenue	2,303	2,829
Other long-term liabilities	1,190	1,377
Stockholders' equity	63,858	73,154
Total liabilities and stockholders' equity	\$ 85,329	\$ 95,048

Contact:

Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina@sternir.com