

# FATE THERAPEUTICS INC

## **FORM 8-K** (Current report filing)

Filed 11/01/17 for the Period Ending 11/01/17

Address	3535 GENERAL ATOMICS COURT SUITE 200 SAN DIEGO, CA, 92121
Telephone	858.875.1803
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SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): November 1, 2017**

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**FATE THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 1, 2017, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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.*

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	<a href="#">Press release dated November 1, 2017</a>

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## 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: November 1, 2017

**FATE THERAPEUTICS, INC.**

By

: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



## Fate Therapeutics Reports Third Quarter 2017 Financial Results

*Clinical Data from First Subjects in VOYAGE Study of FATE-NK100 for Acute Myelogenous Leukemia to be Presented at SITC 2017*

*First-of-Kind iPSC-derived Cancer Immunotherapy Candidates FT500 and FT819 to be Featured in Oral Presentations at 2017 ASH Annual Meeting*

*First Subject Treated in Phase 2 PROTECT Study of ProTmune™ for Prevention of Acute Graft-versus-Host Disease*

**San Diego, CA – November 1, 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 third quarter ended September 30, 2017.

“We are poised to release initial Phase 1 clinical data for FATE-NK100 and ProTmune at prominent scientific conferences during the coming weeks,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “Additionally, we are pleased that two first-of-kind product candidates from our proprietary iPSC-derived cancer immunotherapy pipeline have been selected for oral presentations at the 2017 American Society of Hematology Annual Meeting. Thousands of doses of homogeneous drug product can be produced from a clonal iPSC master cell line in a single manufacturing run. This represents a transformative approach to enable off-the-shelf delivery of cancer immunotherapies that are uniformly engineered and identical in composition from dose-to-dose across patients. At ASH we will be unveiling exciting new preclinical and manufacturing data to support our 2018 path to clinic for iPSC-derived NK- and T-cell product candidates.”

### Recent Highlights & Program Updates

- **Initial Clinical Data from VOYAGE Study of FATE-NK100 in AML to be Presented at SITC 2017** . VOYAGE is an open-label, accelerated dose-escalation clinical trial of FATE-NK100, the Company’s first-in-class adaptive memory natural killer (NK) cell product candidate, for the treatment of refractory or relapsed acute myelogenous leukemia (AML). FATE-NK100 has advanced through the first two of three dose cohorts in VOYAGE. The Company will present the post-manufacturing potency, *in vivo* persistence and anti-tumor activity of FATE-NK100 from the first two subjects at the Society for Immunotherapy of Cancer (SITC) 32<sup>nd</sup> Annual Meeting during a poster session on
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November 10. The peer-reviewed non-clinical data describing the unique properties and anti-tumor activity of FATE-NK100 were published in *Cancer Research* in August.

- **APOLLO Study of FATE-NK100 in Recurrent Ovarian Cancer Open for Enrollment** . In October, enrollment was opened in the APOLLO study of FATE-NK100 for the treatment of women with ovarian cancer resistant to, or recurrent on, platinum-based treatment. APOLLO is designed to evaluate the safety and determine the maximum dose of a single infusion of FATE-NK100 when administered directly into the peritoneum in an outpatient setting. Intraperitoneal delivery of NK cells is a novel strategy intended to promote co-localization with tumor cells and maximize NK cell persistence and anti-tumor activity. Other study endpoints include objective response rate at 28 days post-infusion and progression-free and overall survival.
  - **First Subject Treated in PROTECT Phase 2 Efficacy Stage** . PROTECT is a combined open-label Phase 1 / blinded Phase 2 clinical trial of ProTmune, a next-generation hematopoietic cell graft for patients with hematologic malignancies undergoing allogeneic hematopoietic cell transplantation (HCT). In October, the first subject was treated in the randomized, controlled and blinded Phase 2 stage. The Phase 2 stage is assessing the safety and efficacy of ProTmune in 60 subjects, where subjects are being randomized, in a 1:1 ratio, to receive either ProTmune or a conventional matched unrelated donor mobilized peripheral blood cell graft. The primary efficacy endpoint is incidence of acute graft-versus-host disease (GvHD) by Day 100 post-HCT, where prospective clinical studies have shown that 40% to 80% of patients undergoing matched unrelated donor HCT experience Grades 2-4 acute GvHD.
  - **Day 100 Data from PROTECT Phase 1 Stage to be Presented at 2017 ASH** . The Company will present data on all seven subjects administered ProTmune in the Phase 1 stage of PROTECT at the 59<sup>th</sup> American Society of Hematology (ASH) Annual Meeting during a poster session on December 11. Key clinical outcomes, including incidence of acute GvHD, cancer relapse and survival, at 100 days following HCT will be released. An ASH abstract released today highlighted early data on the first five Phase 1 subjects, three of whom had not yet reached Day 100, as of a July 31, 2017 data cut-off.
  - **First iPSC-derived T-Cell Product Candidate to be Showcased during Oral Presentation at 2017 ASH** . An oral presentation will describe the generation of CD8 $\alpha\beta$  + T cells from an induced pluripotent stem cell (iPSC) line engineered to express a chimeric antigen receptor (CAR). This breakthrough was led by Dr. Michel Sadelain, MD, PhD, Director, Center for Cell Engineering, Memorial Sloan Kettering Cancer Center (MSK), under the Company's multi-year sponsored research collaboration with MSK. The Company's first iPSC-derived CAR T-cell product candidate FT819, which is derived from a clonal iPSC master cell line engineered to express a CAR targeting CD19 and edited to remove T-cell receptor (TCR) expression, is undergoing preclinical development.
  - **First iPSC-derived NK Cell Product Candidate FT500 to be Showcased during Oral Presentation at 2017 ASH** . An oral presentation by Jeffrey S. Miller, MD, Deputy Director of the Masonic Cancer Center, University of Minnesota, will describe the production under current good manufacturing practice (cGMP) conditions of FT500, the Company's first-of-kind NK cell product candidate derived
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from a clonal iPSC master cell line . Fate Therapeutics plans to file a landmark Investigational New Drug (IND) application with the U.S. Food & Drug Administration (FDA) in the first quarter of 2018 to initiate first-in-human clinical investigation of FT500 in combination with FDA-approved checkpoint inhibitors for the treatment of advanced solid tumors.

- **Key Patent Issued for Enhanced Genetic Engineering of CD34+ Cells .** In August, the Company announced that the U.S. Patent and Trademark Office issued U.S. Patent No. 9,675,641 covering the use of prostaglandins as viral transduction enhancers for the genetic modification of CD34 + hematopoietic cells. The patent, which broadly covers methods of using prostaglandins to enhance *ex vivo* genetic engineering of hematopoietic cells using viral vectors, is owned by the Indiana University Research and Technology Corporation and is licensed exclusively to Fate Therapeutics in all fields. Investigators recently highlighted in Molecular Therapy that this practice consistently increased transduction efficiency in primary CD34+ cells sourced from multiple normal human donors and from patients with  $\beta$ -thalassemia or sickle cell disease, concluding that prostaglandins may be critical to ensuring successful clinical gene therapy using lentivirus-modified CD34+ cells.

### Third Quarter 2017 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of September 30, 2017 were \$69.2 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. This use was offset by \$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.
  - **Total Revenue:** Revenue was \$1.0 million for the third quarter of 2017 and 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 \$11.4 million for the third quarter of 2017 compared to \$9.4 million for the comparable period in 2016. Operating expenses for the third 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 \$8.6 million for the third quarter of 2017 compared to \$6.8 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, and an increase in facilities costs associated with the expansion of the Company's laboratory space.
  - **G&A Expenses:** General and administrative expenses were \$2.8 million for the third 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 employee compensation and benefits expense, including
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employee stock-based compensation expense, and an increase in facilities costs associated with the expansion of the Company's office space.

- **Shares Outstanding:** Common shares outstanding were 41.5 million as of September 30, 2017 and 41.4 million as of December 31, 2016. Preferred shares outstanding as of September 30, 2017 and 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, Wednesday, November 1, 2017 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 30, 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 9892619. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the Company's website at [www.fatetherapeutics.com](http://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 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. FATE-NK100 is produced through a feeder-free, seven-day manufacturing process during which NK cells sourced from a healthy donor are activated *ex vivo* with pharmacologic modulators.

#### **About ProTmune™**

ProTmune™ is an investigational next-generation hematopoietic cell graft for the prevention of acute graft-versus-host disease (GvHD) in subjects 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 enhance the biological properties and therapeutic function of the graft. Acute GvHD is a severe immunological disease that commonly arises in patients during the first weeks following allogeneic HCT when the newly-transplanted donor immune cells attack the patient's tissues and organs, resulting in a potentially fatal immune system reaction. The disease is the leading cause of early morbidity and mortality in matched unrelated donor transplant, and there are currently no FDA-approved preventive therapies and very few treatment options for acute GvHD. ProTmune has been granted Orphan Drug and Fast Track Designations by the FDA, and Orphan Medicinal Product Designation by the European Medicines Agency.

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### **About Fate Therapeutics' iPSC Product Platform**

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables genetic engineering, high-throughput single-cell isolation and clonal selection of human iPSCs and supports long-term maintenance of human iPSCs as master pluripotent cell lines. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. Similar to master cell lines used for the manufacture of monoclonal antibodies, clonal iPSC master cell lines can serve as a renewable cell source for the consistent and repeated manufacture of homogeneous cell products with the potential to treat many different diseases and 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 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 cell lines, 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](http://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 and the receipt of data from its ongoing clinical trials, the Company's expected product development and regulatory strategy, and associated timelines, for its iPSC-derived product candidates, the therapeutic potential of ProTmune and FATE-NK100, 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, 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 ongoing clinical studies, the risk that the Company may cease or delay preclinical or clinical development for any of its existing or future product candidates for a variety of reasons (including requirements that may be imposed by

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regulatory authorities and requirements for regulatory approval, difficulties or delays in subject enrollment in current and planned clinical trials, difficulties in manufacturing and 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 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](http://www.fatetherapeutics.com)) and its investor relations website ([ir.fatetherapeutics.com](http://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.

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**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 1,026	\$ 1,026	\$ 3,079	\$ 3,375
Operating expenses:				
Research and development	8,578	6,804	24,471	20,222
General and administrative	2,788	2,611	8,489	7,462
Total operating expenses	11,366	9,415	32,960	27,684
Loss from operations	(10,340)	(8,389)	(29,881)	(24,309)
Other income (expense):				
Interest income	152	37	400	95
Interest expense	(378)	(385)	(856)	(1,308)
Loss on extinguishment of debt	(118)	—	(118)	—
Total other expense, net	(344)	(348)	(574)	(1,213)
Net loss	\$ (10,684)	\$ (8,737)	\$ (30,455)	\$ (25,522)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	26	(8)	(12)	3
Comprehensive loss	\$ (10,658)	\$ (8,745)	\$ (30,467)	\$ (25,519)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.27)	\$ (0.74)	\$ (0.85)
Weighted-average common shares used to compute basic and diluted net loss per share	41,428,845	32,090,174	41,407,995	29,920,075

**Condensed Consolidated Balance Sheets**  
(in thousands)

	September 30, 2017	December 31, 2016
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 43,231	\$ 88,609
Short-term investments and related maturity receivables	25,983	3,503
Prepaid expenses and other current assets	825	1,211
Total current assets	70,039	93,323
Long-term assets	2,636	1,725
Total assets	\$ 72,675	\$ 95,048
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,611	\$ 4,891
Long-term debt, current portion	—	8,187
Current portion of deferred revenue	2,105	2,105
Other current liabilities	—	4
Total current liabilities	9,716	15,187
Long-term debt, net of current portion	14,789	2,501
Deferred revenue	1,250	2,829
Other long-term liabilities	1,171	1,377
Stockholders' equity	45,749	73,154
Total liabilities and stockholders' equity	\$ 72,675	\$ 95,048

**Contact:**

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