

# FATE THERAPEUTICS INC

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

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Address	3535 GENERAL ATOMICS COURT SUITE 200 SAN DIEGO, CA 92121
Telephone	858.875.1803
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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

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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): March 16, 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))
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**Item 2.02 Results of Operations and Financial Condition.**

On March 16, 2017, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2016. 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	Press release dated March 16, 2017

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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: March 16, 2017

**FATE THERAPEUTICS, INC.**

By :/s/ J. Scott Wolchko

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J. Scott Wolchko

President and Chief Executive Officer

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**EXHIBIT INDEX**

**Exhibit No.**  
99.1

**Description**  
Press release dated March 16, 2017



## Fate Therapeutics Reports Fourth Quarter 2016 Financial Results

*First Subject Treated with ProTmune™ for GvHD Prevention*

*IND Cleared by FDA for FATE-NK100 Natural Killer Cell Product Candidate in AML*

*First-of-Kind Cancer Immunotherapy Derived from Engineered Pluripotent Cell Line to Begin Clinical Translation*

*iPSC-derived NK Cell Research Collaboration Launched with Oslo University Hospital*

**San Diego, CA – March 16, 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 fourth quarter and year ended December 31, 2016.

“The past twelve months has been a period of significant progress for Fate Therapeutics, including advancing two first-in-class product candidates to clinical development and launching our revolutionary induced pluripotent cell platform to enable our ‘one cell, many patients’ approach to cancer immunotherapy. We have recently treated the first subject in our PROTECT study with ProTmune, our next-generation mobilized peripheral blood graft with the potential to change the field of allogeneic hematopoietic cell transplantation, and FDA clearance was granted for clinical investigation of FATE-NK100, our first-in-class adaptive memory natural killer cell product candidate. Additionally, we established collaborations with Dr. Jeffrey S. Miller at the University of Minnesota and Dr. Michel Sadelain at Memorial Sloan Kettering Cancer Center to build our off-the-shelf cancer immunotherapy pipeline using master pluripotent cell lines,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “Looking ahead to a data-rich 2017, having recently raised approximately \$70 million from a leading investor syndicate, we are in a position of financial strength and are poised to be the first company to advance a cancer immunotherapy created from a master pluripotent cell line toward clinical development.”

### Recent Highlights & Program Updates

- **First Subject Treated with ProTmune™ for GvHD Prevention.** The Company’s Phase 1/2 PROTECT study of ProTmune for the prevention of acute graft-versus-host disease (GvHD) has treated its first subject and is open across ten U.S. centers. The Phase 1 stage of the clinical study is expected to enroll up to ten adult subjects with hematologic malignancies undergoing allogeneic mobilized peripheral blood hematopoietic cell transplantation. ProTmune has been granted Fast Track and Orphan Drug Designations by the U.S. Food and Drug Administration (FDA) and Orphan Medicinal Product Designation by the European Medicines Agency.
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- **IND Cleared by FDA for FATE-NK100 in AML.** Enrollment of a first-in-human clinical trial of FATE-NK100 under an investigator-initiated clinical trial is poised to commence at the Masonic Cancer Center, University of Minnesota (UMN). In February 2017, the FDA cleared the Investigational New Drug (IND) application of FATE-NK100 for the treatment of refractory or relapsed acute myelogenous leukemia (AML). An oral presentation at the 58<sup>th</sup> American Society of Hematology Annual Meeting and Exposition in December 2016 featured FATE-NK100 preclinical data. The natural killer (NK) cell product candidate demonstrated enhanced anti-tumor activity across a broad range of liquid and solid tumors, improved persistence and increased resistance to immune checkpoint pathways as compared to current conventional NK cell therapies.
  - **Expanded Collaboration with UMN to Advance hnCD16-iNK Cell Product Candidate.** In February 2017, Fate Therapeutics and UMN expanded their collaboration, initiating the clinical translation of a first-of-kind product candidate, an off-the-shelf cellular immunotherapy created from an induced pluripotent stem cell (iPSC) line for the treatment of cancer. Similar to the manufacture of therapeutic antibodies using master cell lines, the Company's targeted NK cell product candidate is created from a master iPSC line engineered to express a proprietary high-affinity, non-cleavable CD16 (hnCD16) receptor. Preclinical data, which the Company plans to present at the upcoming 2017 Annual Meeting of the American Association for Cancer Research, demonstrates the potential of its hnCD16-iNK cell product candidate to complement standard-of-care monoclonal antibody therapy for the treatment of breast, head and neck, colorectal and certain blood cancers by binding to and selectively killing antibody-coated tumor cells.
  - **Launched iPSC-derived NK Cell Research Collaboration with Oslo University Hospital.** In February 2017, Fate Therapeutics formed a two-year research collaboration with Oslo University Hospital to develop NK cell product candidates expressing certain activating and targeting receptors using master pluripotent cell lines. The collaboration is being led by Karl-Johan Malmberg, M.D., Ph.D., Group Leader of Natural Killer Cell Biology and Cell Therapy, Department of Immunology, who has extensively studied the human NK cell repertoire, including the influence of killer cell immunoglobulin-like receptors, in regulating anti-tumor activity.
  - **Bolstered NK Cell Product and iPSC Platform Intellectual Property.** In December 2016, the Company exclusively licensed intellectual property from UMN covering compositions of a modified CD16, as well as certain chimeric antigen receptors and immune cells expressing such receptors. In addition, in March 2017, the U.S. Patent and Trademark Office issued U.S. Patent No. 9,593,311, which is owned by the Whitehead Institute for Biomedical Research and licensed exclusively to the Company for all therapeutic purposes, protecting cellular compositions comprising an iPSC and a WNT pathway activator. Publications in the pluripotent cell biology field have shown that WNT pathway activation is required to enable single cell isolation and clonal expansion of iPSCs, which are critical steps in generating, engineering and maintaining master pluripotent cell lines.
  - **Completed \$56.7M Common and Preferred Stock Private Placement.** In November 2016, Fate Therapeutics issued 2.82 million shares of non-voting Class A Preferred Stock at \$13.30 per share, each of which is convertible into five shares of common stock upon certain conditions, and 7.24 million shares of common stock at \$2.66 per share. The sale and issuance was pursuant to a securities purchase agreement with certain institutional and accredited investors including Redmile
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Group LLC, BVF Partners L.P., EcoR1 Capital LLC, Franklin Advisers, Inc. and certain members of the Company's Board of Directors and management.

#### Fourth Quarter 2016 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of December 31, 2016 were \$92.1 million compared to \$64.8 million as of December 31, 2015. The increase was primarily driven by net proceeds from the sale of the Company's securities in two private issuances, a \$56.7 million sale and issuance of preferred and common stock in November 2016 and a \$10.2 million sale and issuance of common stock in August 2016. 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 2016 compared to \$1.1 million for the comparable period in 2015. All revenue was derived from the Company's research collaboration and license agreement with Juno Therapeutics.
- **Total Operating Expenses:** Total operating expenses were \$8.7 million for the fourth quarter of 2016 compared to \$8.0 million for the comparable period in 2015. Operating expenses for the fourth quarter of 2016 included \$0.8 million of stock compensation expense, compared to \$0.5 million for the comparable period in 2015.
- **R&D Expenses:** Research and development expenses were \$6.2 million for the fourth quarter of 2016 compared to \$5.4 million for the comparable period in 2015. The increase in R&D expenses was primarily related to an increase in third-party service provider fees to support the Company's clinical development of ProTmune and the preclinical development of its NK cell programs.
- **G&A Expenses:** General and administrative expenses were \$2.5 million for the fourth quarter of 2016 compared to \$2.6 million for the comparable period in 2015. The decrease in G&A expenses was primarily related to a decrease in intellectual property-related expenses.
- **Common Shares Outstanding:** Common shares outstanding as of December 31, 2016 were 41.4 million compared to 28.7 million as of December 31, 2015. Common shares outstanding increased primarily as a result of the Company's sale and issuance of its securities in two private issuances in November and August 2016, respectively.
- **Preferred Shares Outstanding:** Preferred shares outstanding as of December 31, 2016 were 2.82 million. Preferred shares outstanding increased as a result of 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, Thursday, March 16, 2017 at 5:00 p.m. ET to review financial and operating results for the quarter ended December 31, 2016. In order to participate in the conference call, please dial 1-877-303-6235 (domestic) or 1-631-291-4837 (international) and refer to conference ID 85799370. 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.

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**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](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, and partnerships, the Company's progress and plans for its clinical investigation of ProTmune™ and of FATE-NK100, the Company's expected product registration strategy for ProTmune, including its ability to pursue accelerated registration, the ability of ProTmune to prevent, or reduce the incidence or severity of life-threatening complications, including acute graft-versus-host disease and severe viral infections, 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), the risk that the Company's research collaborations may not be successful or may be terminated, 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.

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**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 December 31,		Years Ended December 31,	
	2016	2015	2016	2015
	(unaudited)			
Collaboration revenue	\$ 1,027	\$ 1,076	\$ 4,402	\$ 2,431
Operating expenses:				
Research and development	6,230	5,433	26,452	19,861
General and administrative	2,451	2,555	9,913	10,352
Total operating expenses	<u>8,681</u>	<u>7,988</u>	<u>36,365</u>	<u>30,212</u>
Loss from operations	(7,654)	(6,912)	(31,963)	(27,782)
Other income (expense):				
Interest income	43	3	138	10
Interest expense	(329)	(537)	(1,637)	(2,220)
Total other expense, net	<u>(286)</u>	<u>(534)</u>	<u>(1,499)</u>	<u>(2,210)</u>
Net loss	<u>\$ (7,940)</u>	<u>\$ (7,446)</u>	<u>\$ (33,462)</u>	<u>\$ (29,992)</u>
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(4)	—	(1)	—
Comprehensive loss	<u>\$ (7,944)</u>	<u>\$ (7,446)</u>	<u>\$ (33,463)</u>	<u>\$ (29,992)</u>
Net loss per common share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.26)</u>	<u>\$ (1.05)</u>	<u>\$ (1.18)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>37,216,488</u>	<u>28,687,797</u>	<u>31,754,140</u>	<u>25,484,262</u>

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

	December 31, 2016 (unaudited)	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 88,609	\$ 64,809
Short-term investments	3,503	—
Prepaid expenses and other current assets	1,211	843
Total current assets	93,323	65,652
Long-term assets	1,725	2,306
Total assets	\$ 95,048	\$ 67,958
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,891	\$ 3,435
Long-term debt, current portion	8,187	7,550
Current portion of deferred revenue	2,105	2,401
Other current liabilities	4	55
Total current liabilities	15,187	13,441
Long-term debt, net of current portion	2,501	10,688
Deferred revenue	2,829	4,934
Other long-term liabilities	1,377	857
Stockholders' equity	73,154	38,038
Total liabilities and stockholders' equity	\$ 95,048	\$ 67,958

**Contact:**

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