

**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): August 6, 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 August 6, 2018, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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 August 6, 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: August 6, 2018

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



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

Treated 20th Subject in Phase 2 PROTECT Study of ProTmune

Opened Second Site for Enrollment of FATE-NK100 DIMENSION Study

Submitted First-of-Kind IND to FDA for Universal Off-the-Shelf NK Cell Product FT500

Licensed Novel CAR Constructs from Memorial Sloan Kettering Cancer Center for Off-the-Shelf CAR T-cell Immunotherapies

San Diego, CA– August 6, 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 second quarter ended June 30, 2018.

“Our submission to the FDA of an IND application for FT500, a universal, off-the-shelf NK cell cancer immunotherapy derived from a master iPSC line, is a significant milestone for the Company and the field of cell therapy,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We are excited to be working with the FDA to allow the first U.S. clinical investigation of an iPSC-derived cell therapy and usher in a new era enabling the development, manufacture and delivery of off-the-shelf cell products for the treatment of cancer. I am very pleased with our execution over the first six months of 2018 across the business, as we have also accelerated enrollment in our Phase 2 PROTECT study of ProTmune and expanded our clinical investigation of NK100 to a second leading cancer research center.”

Clinical Programs

- **Treated 20th Subject in Phase 2 PROTECT Study of ProTmune™** During the second quarter of 2018, 14 subjects were treated in the randomized, controlled and double-blinded Phase 2 PROTECT study, which is intended to enroll a total of 60 adult subjects with hematologic malignancies undergoing allogeneic hematopoietic cell transplantation (HCT). Subjects in the Phase 2 PROTECT study are being randomized, in a 1:1 ratio, to receive either ProTmune, the Company’s next-generation hematopoietic cell graft, or a conventional matched unrelated donor cell graft. The Company has submitted an abstract to present clinical data from the seven subjects that were administered ProTmune in the Phase 1 stage of PROTECT, including data on a key secondary endpoint assessing freedom from chronic graft-versus-host disease (GvHD), cancer relapse and death at 1-year following HCT, at the 2018 ASH Annual Meeting.
 - **Expanded Enrollment of FATE-NK100 Dimension Study to Baylor University Medical Center** The Company has now enrolled subjects in the Phase 1 DIMENSION study at two of the nation’s leading
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cancer research centers, Baylor Charles A. Sammons Cancer Center in Dallas and the Masonic Cancer Center, University of Minnesota. The DIMENSION study 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. Three Phase 1 clinical trials of NK100 are currently being conducted in subjects with advanced liquid and solid tumors, and the Company plans to present additional clinical data for NK100 in the second half of 2018.

Universal Off-the-Shelf Cancer Immunotherapy Preclinical Pipeline

- **Submitted First-of-Kind IND Application to FDA for FT500** Within the last thirty days, the Company submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for FT500, a universal, off-the-shelf NK cell product. FT500 is the first product candidate emerging from the Company's industry-leading induced pluripotent stem cell (iPSC) product platform, which uses clonal master iPSC lines as a renewable source for producing off-the-shelf cellular immunotherapies. The Company plans to clinically investigate FT500 in combination with FDA-approved checkpoint inhibitors as a rescue therapy.
- **Gained Rights to Novel CAR Constructs and CRISPR Gene-Editing from MSK** In May, the Company expanded its existing license agreement with Memorial Sloan Kettering Cancer Center (MSK) to further enable the development of off-the-shelf CAR T-cell immunotherapies, including the Company's universal, off-the-shelf CAR19 T-cell product candidate FT819. The newly-licensed portfolio of intellectual property covers certain patents and patent applications relating to novel chimeric antigen receptor (CAR) constructs and off-the-shelf CAR T cells, including the use of CRISPR and other innovative technologies for their production. In connection with amending the license agreement, Fate Therapeutics paid an upfront fee of \$500,000 and issued 500,000 shares of the Company's common stock valued at \$4.8 million to MSK, and MSK returned its entire interest in Tfinity Therapeutics, Inc. to the Company.

Organization

- **Promoted Bob Valamehr, Ph.D. to Chief Development Officer.** Dr. Valamehr joined Fate Therapeutics in 2009 and oversees the Company's iPSC product platform, including the development of the Company's off-the-shelf NK cell and T-cell cancer immunotherapy pipeline. He is first author on the Company's 2014 seminal publication in *Stem Cell Reports* describing the Company's ground-breaking approach to the footprint-free generation, clonal selection and master cell banking of human iPSCs (<https://doi.org/10.1016/j.stemcr.2014.01.014>).
 - **Appointed Michael Lee to Board of Directors.** Mr. Lee is co-founder of and has served as a portfolio manager at Redmile Group, LLC, a health care-focused investment firm based in San Francisco and New York, since 2007.
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Second Quarter 2018 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of June 30, 2018 were \$78.0 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 second 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 \$16.8 million for the second quarter of 2018, compared to \$7.9 million for the same period in 2017. In the second quarter of 2018, the Company incurred a one-time \$5.3 million expense associated with the in-license of additional intellectual property from MSK. The remaining increase in R&D expenses was primarily attributable to an increase in expenses associated with the clinical development of FATE-NK100 and with regulatory and manufacturing activities to support the submission of the FT500 IND application.
- **G&A Expenses:** General and administrative expenses were \$3.8 million for the second quarter of 2018, compared to \$2.7 million for the same period in 2017. The increase in G&A expenses was primarily attributable to an increase in employee compensation associated with growth in headcount and in intellectual property-related expenses.
- **Shares Outstanding:** Common shares outstanding were 53.4 million as of June 30, 2018 and 52.6 million as of December 31, 2017. Preferred shares outstanding as of June 30, 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, Monday, August 6th, 2018 at 5:00 p.m. ET to review financial and operating results for the quarter ended June 30, 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 2383816. 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 patients in an off-the-shelf manner. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 100 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 results of operations, financial condition and sufficiency of its cash and cash equivalents to fund its operations, as well as statements regarding the 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 intended clinical investigation of its iPSC-derived product candidates, including FT500, the timing for the Company's receipt of data from its clinical trials and preclinical studies, the Company's development and regulatory strategy, and the therapeutic and market potential of the Company's product candidates. 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 initiation of, or 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		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Collaboration revenue	\$ 1,027	\$ 1,026	\$ 2,053	\$ 2,053
Operating expenses:				
Research and development	16,816	7,927	28,292	15,893
General and administrative	3,816	2,669	7,420	5,701
Total operating expenses	<u>20,632</u>	<u>10,596</u>	<u>35,712</u>	<u>21,594</u>
Loss from operations	(19,605)	(9,570)	(33,659)	(19,541)
Other income (expense):				
Interest income	376	137	707	248
Interest expense	(425)	(212)	(837)	(478)
Total other expense, net	<u>(49)</u>	<u>(75)</u>	<u>(130)</u>	<u>(230)</u>
Net loss	<u>\$ (19,654)</u>	<u>\$ (9,645)</u>	<u>\$ (33,789)</u>	<u>\$ (19,771)</u>
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(2)	(5)	(12)	(38)
Comprehensive loss	<u>\$ (19,656)</u>	<u>\$ (9,650)</u>	<u>\$ (33,801)</u>	<u>\$ (19,809)</u>
Net loss per common share, basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.23)</u>	<u>\$ (0.64)</u>	<u>\$ (0.48)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>53,130,518</u>	<u>41,406,367</u>	<u>52,947,926</u>	<u>41,397,398</u>

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,162	\$ 88,952
Short-term investments and related maturity receivables	41,857	11,997
Prepaid expenses and other current assets	2,015	1,647
Total current assets	<u>80,034</u>	<u>102,596</u>
Long-term assets	3,121	2,696
Total assets	<u>\$ 83,155</u>	<u>\$ 105,292</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 11,886	\$ 8,932
CIRM award liability	600	—
Long-term debt, current portion	2,011	—
Current portion of deferred revenue	1,776	2,105
Other current liabilities	—	12
Total current liabilities	<u>16,273</u>	<u>11,049</u>
Long-term debt, net of current portion	12,835	14,808
CIRM award liability	400	—
Deferred revenue	—	724
Other long-term liabilities	1,822	1,522
Stockholders' equity	51,825	77,189
Total liabilities and stockholders' equity	<u>\$ 83,155</u>	<u>\$ 105,292</u>

Contact:

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