

**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): November 1, 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 November 1, 2018, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 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 November 1, 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: November 1, 2018

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer



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

Twenty Subjects Treated across Three Phase 1 Studies of FATE-NK100

Entered into Off-the-Shelf, iPSC-derived CAR-T Cell Collaboration with ONO Pharmaceutical

Completed \$144M Common Stock Public Offering

Three Oral and Four Poster Presentations Covering Product Pipeline will be Presented at ASH Annual Meeting

San Diego, CA– November 1, 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 third quarter ended September 30, 2018.

“We continue to see strong momentum in the enrollment of our Phase 2 PROTECT study of ProTmune, and an encouraging set of initial clinical data for FATE-NK100 is emerging across the dose-escalation phases of three Phase 1 clinical trials. In addition, we are poised to achieve a significant milestone for Fate Therapeutics as well as the entire cell therapy field, as we continue working with the FDA on the allowance of our landmark IND application for FT500, a first-of-kind, off-the-shelf NK cell product derived from a clonal master iPSC line,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “At ASH, we plan to share preclinical data across our entire pipeline of off-the-shelf NK cell and CAR T-cell product candidates that demonstrate the unique value in using clonal engineered master iPSC lines as a renewable source for manufacture and delivery of cell-based cancer immunotherapies.”

Clinical Programs

- **Exceeded 50% Enrollment in Phase 2 PROTECT Study of ProTmune™**The randomized, controlled and double-blinded Phase 2 PROTECT study of ProTmune is over 50% enrolled. The clinical trial is intended to enroll a total of 60 adult subjects with hematologic malignancies undergoing allogeneic hematopoietic cell transplantation (HCT). Subjects are being randomized, in a 1:1 ratio, to receive either ProTmune or a conventional matched unrelated donor hematopoietic cell graft. New clinical data from the seven subjects receiving ProTmune in the Phase 1 PROTECT study, including data on key secondary endpoints assessing disease-free survival and freedom from chronic graft-versus-host disease (GvHD), cancer relapse, and death at one-year following HCT, will be featured at the 2018 American Society of Hematology (ASH) Annual Meeting in a poster presentation.
-

- **20th Subject Treated across Three Phase 1 Studies of FATE-NK100.** The twentieth subject has been treated with FATE-NK100, the Company's first-in-class, donor-derived adaptive memory NK cell cancer immunotherapy, across the dose-escalation phases of three Phase 1 clinical trials. At the Society for Immunotherapy of Cancer (SITC) Annual Meeting, the Company plans to hold an investor event and share new clinical data of FATE-NK100, including safety, persistence and anti-tumor activity, in advanced hematologic malignancies and solid tumors. An oral presentation at the 2018 ASH Annual Meeting will describe a next-generation, GMP-compliant protocol, established by Dr. Karl-Johan Malmberg under the Company's research collaboration with Oslo University Hospital, that enables robust *ex vivo* expansion of adaptive memory NK cells having homogeneous expression of a single inhibitory killer cell immunoglobulin-like receptor (KIR).

Universal Off-the-Shelf Cancer Immunotherapy Preclinical Pipeline

- **Submitted First-of-Kind IND Application to FDA for FT500** In July, 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 derived from a clonal master induced pluripotent stem cell (iPSC) line. In response to a request by the FDA, the Company is conducting additional adventitious agents testing of the master iPSC bank used for the production of FT500, and intends to submit these test results to the FDA during the fourth quarter of 2018. Upon FDA allowance of the IND, the Company expects to begin clinical investigation of FT500 in combination with FDA-approved checkpoint inhibitors in subjects with advanced solid tumors.
- **Achieved IND-Enabling Milestone under FT516 CIRM Grant** In September, the Company received a \$1.1 million milestone payment under its California Institute for Regenerative Medicine (CIRM) award for the preclinical development of FT516, a universal, off-the-shelf NK cell product candidate derived from a clonal master iPSC line engineered to uniformly express a high-affinity, non-cleavable CD16 Fc receptor. Since CD16 binds to the Fc region of tumor-targeted antibodies, FT516 can be combined with FDA-approved monoclonal antibody therapy to target a broad spectrum of tumor-associated antigens. The Company expects to submit an IND application to the FDA by the end of 2018 for first-in-human clinical investigation of FT516 in combination with CD20 antibody rituximab and with SLAMF7 antibody elotuzumab.
- **Five Presentations covering iPSC Product Platform Scheduled for ASH.** Two oral presentations, including new preclinical data of FT500 in combination with checkpoint inhibitors and initial preclinical data of engineered iPSC-derived NK cells in combination with target-cell specific engagers, were accepted for presentation at the ASH Annual Meeting. Additionally, three poster presentations on other product candidates emerging from the Company's iPSC product platform, including the Company's first iPSC-derived chimeric antigen receptor (CAR) T-cell (FT819) and CAR NK cell (FT519) product candidates, are scheduled for presentation.

Corporate Highlights

- **Entered into iPSC-derived CAR T-cell Collaboration with ONO Pharmaceutical** In September 2018, the Company entered into a Collaboration and Option Agreement with Ono Pharmaceutical Co. Ltd. for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates. Fate Therapeutics is entitled to receive up to \$70 million during the preclinical
-

option stage of the collaboration. In addition, in connection with the development and commercialization of the product candidates, the Company is eligible to receive up to \$1.2 billion in aggregate milestone payments, plus tiered royalties on net sales by Ono.

- **Extended iPSC Technology Leadership Position to include CRISPR-based Cell Reprogramming.** In September, the Company exclusively licensed intellectual property from the J. David Gladstone Institutes that covers the generation of iPSCs using CRISPR-mediated gene activation. This new approach uses CRISPR to induce pluripotency by directly targeting a specific location of the genome and activating endogenous gene expression, and does not rely on established methods of cellular reprogramming that require the transduction of multiple transcription factors.
- **Completed \$144 Million Common Stock Offering.** In September, the Company closed an underwritten public offering of 10,648,149 shares of its common stock at a public offering price of \$13.50 per share.

Third Quarter 2018 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of September 30, 2018 were \$211.2 million compared to \$100.9 million as of December 31, 2017. The increase was primarily driven by \$134.9 million in net cash proceeds received by the Company from its September 2018 public offering of common stock. These proceeds were offset by the Company's use of cash to fund operating activities.
 - **Total Revenue:** Revenue was \$1.0 million for the third 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 \$13.6 million for the third quarter of 2018, compared to \$8.6 million for the same period in 2017. In the third quarter of 2018, the Company incurred a one-time \$1.4 million expense associated with the in-license of intellectual property from the J. David Gladstone Institutes covering the use of CRISPR for cellular reprogramming and iPSC generation. 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 the preclinical development of the Company's iPSC-derived product candidates, including regulatory and manufacturing activities to support the submission of its FT500 IND application, and in employee compensation associated with growth in headcount.
 - **G&A Expenses:** General and administrative expenses were \$4.1 million for the third quarter of 2018, compared to \$2.8 million for the same period in 2017. The increase in G&A expenses was primarily attributable to an increase in advisory fees, including audit and legal fees, and in employee compensation.
 - **Shares Outstanding:** Common shares outstanding were 64.5 million as of September 30, 2018 and 52.6 million as of December 31, 2017. Preferred shares outstanding as of September 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, Thursday, November 1, 2018 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 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 6998539. 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 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-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 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 manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients. 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 products 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 and FT516, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	\$ 1,026	\$ 1,026	\$ 3,079	\$ 3,079
Operating expenses:				
Research and development	13,637	8,578	41,929	24,471
General and administrative	4,081	2,788	11,501	8,489
Total operating expenses	17,718	11,366	53,430	32,960
Loss from operations	(16,692)	(10,340)	(50,351)	(29,881)
Other income (expense):				
Interest income	339	152	1,046	400
Interest expense	(429)	(378)	(1,266)	(856)
Loss on extinguishment of debt	—	(118)	—	(118)
Total other expense, net	(90)	(344)	(220)	(574)
Net loss	\$ (16,782)	\$ (10,684)	\$ (50,571)	\$ (30,455)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	1	26	(11)	(12)
Comprehensive loss	\$ (16,781)	\$ (10,658)	\$ (50,582)	\$ (30,467)
Net loss per common share, basic and diluted	\$ (0.31)	\$ (0.26)	\$ (0.95)	\$ (0.74)
Weighted-average common shares used to compute basic and diluted net loss per share	54,185,022	41,428,845	53,364,823	41,407,995

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 183,247	\$ 88,952
Accounts receivable	500	—
Short-term investments and related maturity receivables	27,945	11,997
Prepaid expenses and other current assets	2,237	1,647
Total current assets	213,929	102,596
Long-term assets	6,025	2,696
Total assets	\$ 219,954	\$ 105,292
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,874	\$ 8,932
CIRM award liability, current portion	1,284	—
Long-term debt, current portion	3,264	—
Current portion of deferred revenue	3,250	2,105
Other current liabilities	—	12
Total current liabilities	22,672	11,049
Long-term debt, net of current portion	11,601	14,808
CIRM award liability, net of current portion	856	—
Deferred revenue	8,000	724
Other long-term liabilities	2,896	1,522
Stockholders' equity	173,929	77,189
Total liabilities and stockholders' equity	\$ 219,954	\$ 105,292

Contact:

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