
**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): September 14, 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 1.01 Entry into a Material Definitive Agreement.

On September 14, 2018 (the “Effective Date”), Fate Therapeutics, Inc. (“Fate”) entered into a Collaboration and Option Agreement (the “Collaboration Agreement”) with Ono Pharmaceutical Co. Ltd. (“Ono”) for the joint development and commercialization of two off-the-shelf induced pluripotent stem cell (iPSC)-derived chimeric antigen receptor (CAR) T-cell product candidates. The first iPSC-derived CAR T-cell candidate (“Candidate 1”) targets an antigen expressed on certain lymphoblastic leukemias, and the second candidate (“Candidate 2”) targets a novel antigen identified by Ono expressed on certain solid tumors (each a “Candidate” and collectively the “Candidates”).

Pursuant to the Collaboration Agreement, Fate and Ono will jointly conduct research and development activities under a joint development plan, with the goal of advancing each Candidate to a pre-defined preclinical milestone. Fate has granted to Ono an option to obtain an exclusive license under certain intellectual property rights related to Fate’s iPSC product platform to develop and commercialize (a) Candidate 1 in Asia, with Fate retaining rights for development and commercialization in all other territories of the world and (b) Candidate 2 in all territories of the world, with Fate retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby Fate is eligible to share at least 50% of the profits and losses (each, an “Option”). Fate has maintained worldwide rights of manufacture for both Candidates.

For each Candidate, the Option will expire upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for the Candidate and (c) the date that is the later of (i) four years after the Effective Date and (ii) completion of all applicable activities contemplated under the joint development plan (the “Option Period”).

Under the terms of the Collaboration Agreement, Ono has agreed to pay Fate up to \$70 million during the Option Period with respect to the preclinical development of Candidate 1 and Candidate 2, including an upfront payment of \$10 million, research funding of \$20 million, and milestone and option exercise fees totaling up to \$40 million.

Subject to Ono’s exercise of the Options and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, Fate is entitled to receive an aggregate of up to \$285 million in milestone payments for Candidate 1 and an aggregate of up to \$895 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if Fate elects to co-develop and co-commercialize Candidate 2 as described above. Further, Fate is eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono of each Candidate in specified territories, with such royalties subject to certain reductions.

The Collaboration Agreement will terminate with respect to a Candidate if Ono does not exercise its Option for a Candidate within the Option Period, or in its entirety if Ono does not exercise any of its Options for the Candidates within their respective Option Periods. In addition, either party may terminate the Collaboration Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Collaboration Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time beginning on the third anniversary of the Effective Date or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the Option Period, subject to certain limitations. The Collaboration Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the Collaboration Agreement.

The foregoing description of the terms of the Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to the Collaboration Agreement, which Fate intends to file in redacted form with the Securities and Exchange Commission as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2018.

Item 7.01 Regulation FD Disclosures.

On September 17, 2018, Fate issued a press release announcing its entry into the Collaboration Agreement with Ono. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 September 17, 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: September 17, 2018

Fate Therapeutics, Inc.

By: /s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer



Fate Therapeutics Announces Strategic Collaboration with ONO Pharmaceutical to Develop Off-the-Shelf, iPSC-derived CAR-T Cell Cancer Immunotherapies

Option-based Collaboration to Develop Two CAR T-Cell Product Candidates Using Fate's Proprietary iPSC Product Platform

San Diego, CA – September 17, 2018 – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, announced today that it has entered into a collaboration with ONO Pharmaceutical Co., Ltd. for the joint development and commercialization of two off-the-shelf CAR-T cell product candidates. Using Fate Therapeutics' proprietary induced pluripotent stem cell (iPSC) product platform, the two CAR T-cell collaboration candidates will each be derived from a clonal master iPSC line engineered to completely eliminate endogenous TCR expression, insert a chimeric antigen receptor (CAR) into the TRAC locus and incorporate other anti-tumor functionality. This transformative approach enables the cost-effective production of cell-based cancer immunotherapies that are uniformly engineered, extensively characterized and homogeneous in composition, and can be consistently and repeatedly mass produced and delivered to patients in an off-the-shelf manner.

"We are delighted to collaborate with ONO, a global leader in oncology with a long history of developing innovative breakthrough cancer drugs," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "This partnership with ONO enables Fate to further enhance its expertise in targeting solid tumors and to accelerate the global development of our pipeline of off-the-shelf, iPSC-derived CAR-T cell product candidates."

Under the terms of the strategic option agreement, Fate Therapeutics and ONO will jointly advance each iPSC-derived CAR-T cell collaboration candidate to a pre-defined preclinical milestone. The first iPSC-derived CAR T-cell candidate targets an antigen expressed on certain lymphoblastic leukemias, and Fate Therapeutics retains global responsibility for development and commercialization with ONO having an option to assume responsibilities in Asia. The second candidate targets a novel antigen identified by ONO expressed on certain solid tumors, with ONO having an option to assume global responsibility for further development and commercialization and Fate Therapeutics retaining the right to co-develop and co-commercialize the candidate in the United States and Europe. For both collaboration candidates, Fate Therapeutics retains manufacturing responsibilities on a global basis.

"ONO identified Fate Therapeutics as the partner of choice for the generation of off-the-shelf CAR T-cell cancer immunotherapies in our portfolio," said Hiromu Habashita, Corporate Officer, and Executive Director of Discovery & Research of ONO. "We are excited to work with Fate Therapeutics and apply its industry-leading iPSC product platform to develop and deliver the next-generation of CAR T-cell therapies for cancer patients."

Fate Therapeutics will receive an upfront payment and committed research funding during the preclinical option period, and is eligible to receive a preclinical option exercise fee, clinical, regulatory and commercialization milestone payments and tiered royalties on net sales by ONO in connection with the development and commercialization of each collaboration product by ONO in the ONO territory.

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 reproducibly 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 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.

Fate Therapeutics 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 impact, timing, conduct and the potential benefits of the collaboration, including expected funding and payments to be received by Fate Therapeutics under the collaboration, as well as the capabilities, expertise and responsibilities of each of Fate Therapeutics and ONO Pharmaceutical. 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, risks associated with: the success, cost and timing of product development activities under the collaboration; the ability of Fate Therapeutics and ONO Pharmaceutical to obtain regulatory approval for and to commercialize any product candidates developed under the collaboration; regulatory requirements and regulatory developments; the success of competing treatments and technologies; the risk of cessation or delay of any development activities under the collaboration for a variety of reasons; any adverse effects or events, or other negative results, that may be observed in preclinical or clinical development of any product candidates developed through the collaboration; and the risk that funding and payments received by Fate Therapeutics under the collaboration may be less than expected. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Fate Therapeutics' actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in Fate Therapeutics' periodic filings with the Securities and Exchange Commission, including but not limited to Fate Therapeutics' most recently

filed periodic report, and from time to time in Fate Therapeutics' press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and, except as required by law, 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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