FATE THERAPEUTICS INC
Form 8-K
September 18, 2018

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 | 001-36076 | 65-1311552 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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.

| Exhibit No. | Description |
| --- | --- |
| 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