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 07, 2022

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)**	**(IRS Employer Identification No.)**

12278 Scripps Summit Drive **San Diego, California** **(Address of Principal Executive Offices)**	**92131** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 858 875-1800

(Former Name or Former Address, if Changed Since Last Report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $.001 par value	FATE	NASDAQ Global Market

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 November 7, 2022, Fate Therapeutics, Inc. ("Fate") and Ono Pharmaceutical Co., Ltd. ("Ono") entered into a letter agreement ("Letter Agreement") in connection with the Collaboration and Option Agreement between Fate and Ono dated September 14, 2018, as amended by a letter agreement dated December 4, 2020 and an amendment dated June 28, 2022 (the "Agreement").

Pursuant to the Agreement, as amended by the Letter Agreement, Fate and Ono are conducting research for the joint development and commercialization of off-the-shelf iPSC-derived chimeric antigen receptor (CAR) NK cell and T-cell product candidates targeting two solid tumor antigens. The first solid tumor antigen program targets human epidermal growth factor receptor 2 (HER2) for which the companies are conducting preclinical development of an off-the-shelf, iPSC-derived CAR T-cell candidate ("Collaboration Candidate 2"). Fate has granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize Collaboration Candidate 2 in all territories of the world, with Fate retaining the option to co-develop and co-commercialize Collaboration Candidate 2 in the United States and Europe under a joint arrangement with Ono.

Pursuant to the Letter Agreement, both Fate and Ono exercised their respective options to Collaboration Candidate 2, and accordingly Ono is obligated to pay Fate an option exercise fee of $12.5 million under the Agreement.

The foregoing description of the terms of the Letter Agreement does not purport to be complete and is qualified in its entirety by reference to the Letter Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 7, 2022, Fate issued a press release announcing its entry into the Letter Agreement with Ono. A copy of the press release is being furnished as Exhibit 99.1 to this Current 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
10.1	Letter Agreement, dated November 7, 2022, by and between Fate Therapeutics, Inc. and Ono Pharmaceutical Co., Ltd.
99.1	Press Release dated November 7, 2022

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.

FATE THERAPEUTICS, INC.

Date: November 7, 2022

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

ONO PHARMACEUTICAL CO., LTD.
8-2, Kyutaromachi 1-Chome, Chuo-ku, Osaka-shi 541-8564, JAPAN
TEL : 81-6-6263-5670 FAX : 81-6-6263-2976

November 7, 2022

Fate Therapeutics, Inc.
Corporate Headquarters
12278 Scripps Summit Drive
San Diego, CA 92131
United States of America
Attention: Mr. Scott Wolchko

Re: Amendment to Collaboration and Option Agreement with respect to Collaboration Candidate 2

Dear Mr. Scott Wolchko:

Reference is made to Collaboration and Option Agreement dated September 14, 2018 (the "**Agreement**") entered into by FATE Therapeutics, Inc. ("**FATE**") and Ono Pharmaceutical Co., Ltd. ("**ONO**"), as amended to date. Unless otherwise expressly defined in this letter agreement (the "**Amendment**"), the defined terms used or referenced herein have the meaning ascribed to such terms in the Agreement. The Amendment shall be effective on November 7, 2022 ("**Amendment Effective Date**").

In consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound to amend certain terms of the Agreement, as expressly provided in this Amendment, agree as follows:

1. ONO hereby exercise the ONO Option for Collaboration Candidate 2;

2. FATE shall be deemed to have exercised, and hereby does exercise, the CDCC Option with respect to Collaboration Candidate 2; and

3. the exercise of the ONO Option for Collaboration Candidate 2 and the exercise of the CDCC Option with respect to Collaboration Candidate 2 both shall be effective as of the Amendment Effective Date.

This Amendment together with the Agreement (incorporating all schedules and exhibits) constitutes the entire agreement between the Parties relating to its subject matter. Each Party represents and warrants to the other Party as of the execution of this Amendment, that (i) such Party has taken all necessary action on its part required to authorize the execution and delivery of this Amendment and the performance of its obligations hereunder, and this Amendment constitutes a

legal, valid and binding obligation of such Party that is enforceable against it in accordance with the terms and conditions hereof; and (ii) the execution, delivery and performance of this Amendment by such Party (a) will not constitute a default under, or conflict with, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, (b) violate any Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and (c) is not prohibited or limited by, and shall not result in the breach of or a default under, any provision of the certificate or articles of incorporation or bylaws of such Party. Any breach of the foregoing representation and warranty will be deemed to be a breach of the Agreement.

Save as explicitly amended by this Amendment, all other terms, conditions and provisions of the Agreement will continue in full force and effect in accordance with the terms set forth therein. In the event of a conflict of terms between this Amendment and the Agreement, the terms of this Amendment shall control. Signatures transmitted via PDF shall be treated as original signatures.

Sincerely,

ONO Pharmaceutical Co., Ltd.
By: /s/ Toichi Takino
Name: Toichi Takino, Ph.D.
Title: Member of the Board of Directors,
Senior Executive Officer/Executive Director, Discovery & Research

Accepted and agreed by:

FATE Therapeutics, Inc.
By: /s/ J. Scott Wolchko
Name: Scott Wolchko
Title: President & Chief Executive Officer

Fate Therapeutics Announces Exercise by ONO Pharmaceutical of Option to HER2-targeted CAR T-Cell Product Candidate for Solid Tumors

Multiplexed-engineered, iPSC-derived CAR T-cell Product Candidate Demonstrated Broad, Potent and Specific CAR Activity Across Multiple Preclinical Solid Tumor Models

Fate and ONO to Jointly Develop and Commercialize FT825/ONO-8250 in U.S. and Europe with ONO having Exclusive Rights in Rest of World

San Diego, CA – **November 7, 2022** – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for patients with cancer, today announced that ONO Pharmaceutical Co., Ltd. (ONO) has exercised its option to FT825/ONO-8250, a multiplexed-engineered, iPSC-derived, chimeric antigen receptor (CAR) T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors. The preclinical product candidate incorporates multiple functional elements to enhance the activity and overcome unique challenges in treating solid tumors with cell-based cancer immunotherapies.

“We are encouraged by the compelling preclinical data package generated for FT825/ONO-8250 under our collaboration, which combines the antigen binder that ONO provides and Fate’s industry-leading iPSC product platform to overcome the challenges in solid cancer treatment,” said Toichi Takino, Senior Executive Officer / Executive Director, Discovery & Research of ONO. “We look forward to initiating clinical development of the off-the-shelf, iPSC-derived CAR T-cell product candidate with the aim of delivering benefit to patients with some of the most difficult to treat cancers.”

Under the terms of the Collaboration and Option Agreement, Fate will receive a milestone payment in connection with ONO’s exercise of its option to FT825/ONO-8250. The parties will jointly develop and commercialize FT825/ONO-8250 in the U.S. and Europe, and ONO maintains exclusive development and commercialization rights for FT825/ONO-8250 in the rest of the world. Fate is eligible to receive clinical, regulatory and commercial milestone payments as well as tiered royalties on net sales outside of the United States and Europe by ONO. The parties recently expanded their collaboration to initiate preclinical development of an additional program targeting a second solid tumor antigen.

“Over the past four years, we have worked closely with ONO to discover and integrate novel functional elements into our iPSC-derived CAR T-cell product platform that are specifically designed to address challenges in treating solid tumors, including cell trafficking and immune cell suppression in the tumor microenvironment,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “The preclinical data indicate FT825/ONO-8250 has a highly-differentiated therapeutic profile, including

exhibiting anti-tumor activity against HER2-low tumor cells. We are excited to initiate IND-enabling activities under our collaboration with ONO with the goal of submitting an IND application to FDA in 2023."

Although CAR T-cell therapy has shown significant efficacy in treating hematologic malignancies, its wider application to solid tumors has been hampered by tumor-associated antigen heterogeneity, inefficient CAR T-cell trafficking to the tumor, and immunosuppression inherent to the tumor microenvironment. The Company's multiplexed-engineered, iPSC-derived CAR T-cell product platform is designed to specifically address these challenges and enable the safe and effective treatment of solid tumors as monotherapy and in combination with monoclonal antibody therapy. At the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting to be held from November 8-12, 2022 in Boston, the Company is presenting a poster presentation of FT825/ONO-8250 entitled "*Off-the-shelf iPSC-derived CAR-T cells containing seven functional edits overcome antigen heterogeneity, improve trafficking and withstand immunosuppression associated with failed tumor treatment"* (Abstract ID: 304; November 11, 2022, 9:00 AM – 9:00 PM), which highlights the incorporation of a synthetic CXCR2 receptor to promote cell trafficking, a synthetic TGFβ receptor to redirect immunosuppressive signals in the tumor microenvironment, and a synthetic interleukin-7 receptor fusion protein to induce T-cell activation into its iPSC-derived CAR T-cell product platform.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, engineered, homogeneous cell products that are designed to be administered with multiple doses to deliver more effective pharmacologic activity, including in combination with 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 engineered 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 for patient treatment. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 350 issued patents and 150 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 patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). 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 advancement of, plans related to, and the therapeutic potential of the Company's product candidates, the Company's clinical development strategies, and the Company's plans for the clinical investigation of its product candidates, including FT825/ONO-8250. 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 possibility that the results observed in studies of its product candidates, including preclinical studies and clinical trials of any of its product candidates, will not be observed in ongoing or future studies involving these product candidates; 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.

Contact:

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