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): June 28, 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 June 28, 2022 (the "Effective Date"), Fate Therapeutics, Inc. ("Company") entered into an Amendment 01 to Collaboration and Option Agreement (the "Amendment") with Ono Pharmaceutical Co. Ltd. ("Ono"). The Amendment amends the Collaboration and Option Agreement entered into between the Company and Ono on September 14, 2018 (the "Collaboration Agreement") in order to expand the Company's off-the-shelf induced pluripotent stem cell (iPSC)-derived, cell-based cancer immunotherapy collaboration with Ono to include the development of chimeric antigen receptor (CAR) NK cell collaboration candidates. Under the terms of the Amendment, the Company will advance iPSC-derived CAR NK and CAR T-cell collaboration candidates to a pre-defined preclinical milestone, at which point Ono has an option to assume responsibility for worldwide development and commercialization with the Company retaining the right to jointly develop and commercialize in the United States and Europe. The Company retains all rights of manufacture of collaboration products on a global basis.

Pursuant to the Amendment, the parties have agreed that Ono will contribute novel binding domains targeting a second solid tumor antigen, and the Company and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing collaboration candidates targeting such solid tumor antigen to a pre-defined preclinical milestone. Ono has, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize such collaboration candidates in all territories of the world, with the Company retaining the right to co-develop and co-commercialize such collaboration candidates in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses.

The Company will continue to receive committed research and development funding from Ono through September 2024, and is eligible to receive a preclinical option exercise fee as well as clinical, regulatory and commercialization milestone payments from Ono in connection with the development and commercialization of collaboration products. In addition, the Company continues to be eligible to receive tiered royalties on net sales by Ono of each collaboration product in the ONO Territory (as defined in the Collaboration Agreement).

The foregoing description of the terms of Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, which the Company 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 June 30, 2022.

Item 7.01 Regulation FD Disclosure.

On June 28, 2022, the Company issued a press release announcing its entry into the Amendment 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 June 28, 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: June 30, 2022

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

Fate Therapeutics Announces Expansion of Solid Tumor Collaboration with ONO Pharmaceutical for Off-the-Shelf, iPSC-derived CAR NK and CAR T-Cell Cancer Immunotherapies

ONO to Contribute Novel Binding Domains for a Second Solid Tumor Antigen to the Collaboration

Expanded Partnership Enables Development of both CAR NK and CAR T-cell Collaboration Candidates for Solid Tumors

San Diego, CA – June 28, 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 it has expanded its off-the-shelf, iPSC-derived, cell-based cancer immunotherapy collaboration with ONO Pharmaceutical Co., Ltd. (ONO) to include the development of chimeric antigen receptor (CAR) NK cell collaboration candidates. In addition, as part of the collaboration's expansion, ONO will contribute novel binding domains targeting a second solid tumor antigen. Under the original Collaboration and Option Agreement entered into between Fate and ONO in September 2018, ONO has contributed novel binding domains targeting an initial solid tumor antigen, and Fate is currently conducting preclinical development of a multiplexed-engineered, iPSC-derived CAR T-cell product candidate for solid tumors.

"Our collaboration with ONO has focused on driving innovation in the field of cell therapy for solid tumors, and we are excited by the preclinical data we have observed with our first iPSC-derived CAR T-cell product candidate," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We are impressed with the differentiated antigen binders that ONO has contributed to the partnership, and we are pleased to expand our collaboration to initiate preclinical development of collaboration products targeting a second solid tumor antigen."

Under the terms of the amended Collaboration and Option Agreement, Fate will advance iPSC-derived CAR NK and CAR T-cell product candidates to a pre-defined preclinical milestone, at which point ONO has an option to assume responsibility for worldwide development and commercialization with Fate retaining the right to jointly develop and commercialize in the United States and Europe. Fate retains all rights of manufacture of collaboration products on a global basis.

“The first multiplexed-engineered, iPSC-derived CAR T-cell product candidate under our collaboration with Fate Therapeutics incorporates multiple mechanisms of action designed to specifically address solid tumors and is successfully advancing toward clinical development,” said Toichi Takino, Senior Executive Officer / Executive Director, Discovery & Research of ONO. “Based on the collaboration progress and Fate’s proven ability to develop innovative product candidates, we are excited to expand our collaboration to include a second solid tumor target and to continue our work with Fate in developing first-in-class, off-the-shelf CAR NK and CAR T-cell therapies for cancer patients.”

Fate will continue to receive committed research funding from ONO during the preclinical option period, and is eligible to receive a preclinical option exercise fee as well as clinical, regulatory and commercialization milestone payments from ONO in connection with the development and commercialization of each product candidate. In addition, Fate is eligible to receive tiered royalties on net sales by ONO of each product candidate in the ONO territory.

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 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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