
**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): May 15, 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 May 15, 2018 (the “Effective Date”), Fate Therapeutics, Inc. (the “Company”) entered into an Amended and Restated Exclusive License Agreement (the “Amended MSK License”) with Memorial Sloan Kettering Cancer Center (“MSK”). The Amended MSK License amends and restates the Exclusive License Agreement entered into between the Company and MSK on August 19, 2016 (the “Original MSK License”).

In connection with the entry into the Original MSK License, the Company and MSK established Tfinity Therapeutics, Inc. (“Tfinity”), in which the Company owned a majority interest.

Pursuant to the Amended MSK License, MSK has granted to the Company additional licenses to certain patents and patent applications relating to new chimeric antigen receptor (CAR) constructs and off-the-shelf CAR T cells, including the use of CRISPR and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. The Company continues to hold exclusive licenses to certain patents and patent applications relating to off-the-shelf T-cell immunotherapies, including CAR T cells manufactured from induced pluripotent stem cells, that were granted under the Original MSK License. Additionally, the Company has the right to grant sublicenses to the licensed rights in accordance with the terms of the Amended MSK License.

In consideration for the additional rights granted under the Amended MSK License, the Company has agreed to issue to MSK 500,000 shares of the Company’s Common Stock, par value \$0.001 per share (the “MSK Shares”) and, in return, MSK has agreed to return its entire interest in Tfinity to the Company. As a result, as of the Effective Date, Tfinity is a wholly-owned subsidiary of the Company. The MSK Shares are being issued pursuant to an exemption from registration under the Securities Act of 1933, as amended (the “Securities Act”), in reliance on Section 4(a)(2) of the Securities Act regarding transactions by an issuer not involving a public offering. Pursuant to the Amended MSK License, the Company is obligated to register the MSK Shares for resale within 18 months of the Effective Date.

Pursuant to the Amended MSK License, the Company also agreed to pay an upfront fee of \$500,000 and is obligated to pay a royalty to MSK on net sales of licensed products and milestone payments upon the achievement of specified clinical and regulatory milestones. Additionally, under the terms of the Amended MSK License, in the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive additional milestone payments, where such payments are owed to MSK contingent upon an increase in the price of the Company’s Common Stock relative to the price of the Common Stock as of the Effective Date, as determined in accordance with the terms of the Amended MSK License. The Company is also obligated to pay MSK a percentage of certain sublicense income received by the Company.

The foregoing description of the terms of the Amended MSK License does not purport to be complete and is qualified in its entirety by reference to the Amended MSK License, 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, 2018.

Item 7.01 Regulation FD Disclosures.

On May 16, 2018, the Company issued a press release announcing its entry into the Amended MSK License with MSK. 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 May 16, 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: May 18, 2018

Fate Therapeutics, Inc.

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



Fate Therapeutics and Memorial Sloan Kettering Cancer Center Expand Scope of License Agreement to include Gene-edited T-cell Immunotherapies

Dr. Michel Sadelain to Present Preclinical Data from iPSC-derived, TCR-less, CAR T-cell Collaboration at ASGCT 2018

San Diego, CA – May 16, 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 the Company has gained access to additional intellectual property from Memorial Sloan Kettering Cancer Center (MSK) that enables the development of gene-edited T-cell immunotherapies. The newly-licensed portfolio of intellectual property covers new chimeric antigen receptor (CAR) constructs as well as off-the-shelf CAR T cells, including the use of CRISPR and other innovative technologies for their production.

Fate Therapeutics is utilizing gene editing under its ongoing collaboration for the research and development of off-the-shelf CAR T-cell immunotherapies with Michel Sadelain, M.D., Ph.D., Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at MSK. At the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting, Dr. Sadelain will present preclinical data on FT819, an off-the-shelf, TCR-less, CD19 CAR T-cell product manufactured from a clonal master induced pluripotent stem cell (iPSC) line.

“Engineering stem cells and using master iPSC lines for the renewable production of off-the-shelf CAR T cells has the potential to advance the cancer immunotherapy landscape,” said Dr. Sadelain. “We are pleased with the breakthrough discoveries accomplished under our ongoing collaboration with Fate Therapeutics, and look forward to continuing our advancement together of off-the-shelf CAR T-cell products toward clinical development.”

The use of clonal master iPSC lines can overcome the complexity, heterogeneity and substantial costs associated with using cells from a patient or an allogeneic donor. Instead, iPSC-derived T-cell immunotherapies can be consistently and repeatedly mass produced and delivered in an off-the-shelf manner, significantly reducing the cost of, and time to, patient treatment.

“The use of a gene-edited master iPSC line for the manufacture of off-the-shelf T-cell immunotherapies ensures complete removal of endogenous TCR expression, which is critical to avoid the life-threatening complication of graft-versus-host disease that is seen in allogeneic T-cell therapy,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “The incorporation of these latest MSK technologies into our development of FT819 and our iPSC product platform advances our leadership

position in developing off-the-shelf T-cell immunotherapies with improved safety, enhanced potency and expanded therapeutic reach.”

Fate Therapeutics has exclusively licensed from MSK intellectual property covering the production and composition of iPSC-derived T cells for human therapeutic use. In addition, Fate Therapeutics owns an extensive intellectual property portfolio that broadly covers compositions and methods for the genome editing of iPSCs using CRISPR and other nucleases, including the use of CRISPR to insert a CAR in the TRAC locus for endogenous transcriptional control.

About FT819

FT819 is a universal, off-the-shelf, dual-targeted CAR T-cell product that is manufactured from a clonal master iPSC line. The line is engineered to completely eliminate expression of the T-cell receptor, to preferentially regulate CAR19 expression by inserting the CAR into the T-cell receptor constant (TRAC) locus, and to uniquely express a recombinant CD16 Fc receptor. In preclinical studies, FT819 exhibits a target-specific T-cell response *in vitro* when challenged with CD19-positive tumor cells and displays enhanced production of effector cytokines and cytolytic proteins. In addition, FT819 uniquely elicits antibody-dependent cell-mediated cytotoxicity *in vitro* against CD19-negative, CD20-positive tumor cells with rituximab, a monoclonal antibody targeting CD20. This dual-targeted approach of FT819 can substantially broaden the cell product’s therapeutic reach and overcome CD19 antigen escape through combination with other proven cancer treatments.

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 consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in a cost-effective, off-the-shelf manner. Fate Therapeutics’ iPSC product platform is supported by an intellectual property portfolio of over 90 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 collaboration with Memorial Sloan Kettering Cancer Center, including the therapeutic potential of any T-cell immunotherapies developed under the collaboration, the scope of the Company's intellectual property rights, the advancement of and plans related to its research and development of iPSC-derived T-cell immunotherapies and off-the-shelf CAR T-cell products, including the safety and therapeutic potential of such therapies, the Company's progress and plans for the manufacture and development of FT819, and the Company's expected product development and regulatory strategy, and associated timelines, for its iPSC-derived cellular immunotherapies and off-the-shelf CAR T-cell products, including FT819. 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 preclinical studies of any of its iPSC-derived cellular immunotherapies, including any off-the-shelf CAR T-cell products, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay development of any of its iPSC-derived cellular immunotherapies, including any off-the-shelf CAR T-cell products, 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 in manufacturing or supplying any of the its iPSC-derived cellular immunotherapies, including any off-the-shelf CAR T-cell products, for preclinical or clinical testing, difficulties or delays in subject enrollment in planned clinical trials, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that any of its iPSC-derived cellular immunotherapies, including any off-the-shelf CAR T-cell products, may not be suitable for therapeutic applications and may not provide the anticipated therapeutic benefits. 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.

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