## 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): August 03, 2022

# 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 (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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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:

	Trading	
Title of each class	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  $\Box$ 

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 2.02 Results of Operations and Financial Condition.

On August 3, 2022, Fate Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2022. A copy of the press release is attached as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, 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 August 3, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### 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 thereunto duly authorized.

#### FATE THERAPEUTICS, INC.

Date: August 3, 2022 By:

<u>/s/ J. Scott Wolchko</u> J. Scott Wolchko President and Chief Executive Officer



### Fate Therapeutics Reports Second Quarter 2022 Financial Results and Highlights Operational Progress

FT596+R Enrollment Ongoing in Multi-dose, Multi-cycle Cohorts for R/R BCL; Initiated Study Start-up for Investigation of FT596+R-CHOP in Newly-diagnosed Patients with Aggressive BCL

FT516 RMAT Meeting Scheduled with FDA for 3Q22 to Discuss Registrational Pathways for R/R BCL

First Patient Treated with FT536 iPSC-derived CAR MICA/B NK Cell Product Candidate for Solid Tumors

Commercial Option Exercised by Janssen for First Antigen Program; First IND Submission for CAR NK Cell Collaboration Product Planned for 2H22

Expanded Research Collaboration with ONO Pharmaceutical for Preclinical Development of Second Solid Tumor Program

**San Diego, CA** –**August 3, 2022** – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for patients with cancer, today reported business highlights and financial results for the second quarter ended June 30, 2022.

"We continue to make important strides across our clinical, regulatory, and manufacturing operations to support pivotal readiness of our iPSC-derived NK cell product candidates for B-cell lymphoma, and are looking forward to meeting with the FDA in the third quarter to discuss registrational pathways for the treatment of relapsed / refractory aggressive lymphomas, including for patients that have previously failed CD19-targeted CAR T-cell therapy," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We are also excited that clinical investigation of FT536 has initiated to assess the targeting of oncogenic and cellular stress ligands, a novel pan-tumor-targeting strategy with the potential to overcome common mechanisms of tumor escape that frequently emerge in patients with advanced solid tumors. Finally, we continue to drive our collaborations with Janssen and Ono with strong momentum, and are well positioned to achieve significant milestones and advance three multiplexed-engineered, CAR-targeted cell collaboration candidates into clinical development over the next 12 months."

#### **B-cell Malignancy Disease Franchise**

**FT596+R Enrollment Ongoing in Single- and Multi-dose, Multi-cycle Cohorts for R/R BCL.** The Company's multicenter Phase 1 study of FT596 in combination with rituximab (FT596+R) for relapsed / refractory (r/r) B-cell lymphoma (BCL) is currently enrolling patients in single- and two-dose cohorts at up to 1.8 billion cells per dose. Each cohort permits eligible patients to receive multiple treatment cycles. Upon further clearance of dose-limiting toxicities (DLTs), the clinical protocol permits additional assessment of dose and schedule, including the opening of three-dose cohorts as well as continued dose escalation and expansion.

- Study Start-up Initiated for FT596+R-CHOP in First-line Aggressive B-cell Lymphoma. The Company has submitted a new clinical protocol to the FT596 Investigational New Drug (IND) application and has initiated study start-up to assess the safety and activity of adding FT596 to R-CHOP, the standard first-line immunochemotherapy for patients with aggressive lymphomas. The proposed treatment schema includes administering up to six doses of FT596, with each dose being administered with each of six standard cycles of R-CHOP. The objective of the Phase 1 study is to inform the feasibility of developing FT596, without conditioning chemotherapy, for the treatment of patients with newly-diagnosed aggressive BCL in the outpatient community setting.
- **FT516 Multi-disciplinary RMAT Meeting Schedule for 3Q22.** The Company is scheduled to hold its FT516 Regenerative Medicine Advanced Therapy (RMAT) Type B multi-disciplinary meeting with the U.S. Food and Drug Administration (FDA) in the third quarter of 2022. The meeting agenda includes discussion of registrational pathways for the treatment of patients with aggressive lymphomas, including patients who have relapsed or are refractory to FDA-approved CD19-directed chimeric antigen receptor (CAR) T-cell therapy. No standard therapies are available for these post-CAR T-cell therapy patients, and recent retrospective analyses of real-world data presented at the 2021 Annual Meeting of the American Society of Hematology demonstrate extremely poor treatment outcomes with complete response rates of administered therapies ranging from 5% to 25% and overall survival ranging from 5.2 months to 7.5 months.
- **FT516+R Enrollment Ongoing in Multiple Multi-dose, Multi-cycle, Disease-specific Expansion Cohorts for R/R BCL.** The Company's multicenter Phase 1 study of FT516 in combination with rituximab (FT516+R) for r/r BCL is currently enrolling patients in multiple disease-specific, multi-dose, multi-cycle expansion cohorts at 900 million cells per dose, including patients with r/r aggressive lymphomas who have previously been treated with CD19-targeted CAR T-cell therapy.
- **FT819 Enrollment Ongoing in Third Single-dose and Second Multi-dose Escalation Cohorts.** The Company is conducting a landmark Phase 1 study of FT819, the first-ever T-cell therapy manufactured from a clonal master induced pluripotent stem cell (iPSC) line to undergo clinical investigation. The product candidate's clonal master iPSC line is created from a single iPSC that has a novel CD19-targeted 1XX CAR construct (1XX-CAR19) integrated into the T-cell receptor alpha constant (TRAC) locus, ensuring complete bi-allelic disruption of T-cell receptor expression and promoting uniform CAR expression. Dose escalation is ongoing in the third single-dose escalation cohort of 360 million cells and in the second three-dose escalation cohort of 60 million cells per dose for r/r BCL.

#### Multiple Myeloma Franchise

- **FT576 Enrollment Ongoing in Phase 1 Study for R/R MM.** The multicenter Phase 1 study is designed to assess single-dose and multi-dose treatment schedules of FT576 as monotherapy and in combination with daratumumab (FT576+D) for the treatment of r/r multiple myeloma (MM). There were no DLTs observed in the second single-dose escalation cohort (300 million cells) as monotherapy or in the first single-dose escalation cohort (100 million cells) in combination with daratumumab; and no events of any grade of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), or graft-versus-host disease (GvHD) have been reported. Enrollment is currently ongoing in the two-dose escalation cohorts with FT576 administered on Days 1 and 15.
- **FT538 Enrollment Ongoing in Third Multi-dose Escalation Cohort.** The Company's Phase 1 study is designed to assess three once-weekly doses of FT538 in combination with daratumumab for the treatment of r/r MM, and is currently enrolling patients in the third multi-dose escalation cohort (1

#### AML Disease Franchise

• **FT538 Enrollment Ongoing in Fourth Multi-dose Escalation Cohort.** The Company's Phase 1 study is designed to assess three once-weekly doses of FT538 as monotherapy for the treatment of r/r acute myeloid leukemia (AML), and is currently enrolling patients in the fourth multi-dose escalation cohort (1.5 billion cells per dose). In addition, an investigator-initiated study of FT538 in combination with the CD38-targeted monoclonal antibody daratumumab, which is designed to assess the therapeutic potential of targeting CD38+ leukemic blasts, is enrolling patients in the fourth multi-dose escalation cohort (1.5 billion cells per dose).

#### Solid Tumor Franchise

- **First Patient Treated with FT536 CAR MICA/B-targeted NK Cell Product Candidate.** The multicenter Phase 1 study is designed to assess a multi-dose, multi-cycle treatment schedule as monotherapy and in combination with monoclonal antibody therapy for the treatment of advanced solid tumors. FT536 uniquely targets the alpha-3 domains of the major histocompatibility complex (MHC) class I related proteins A (MICA) and B (MICB); a novel targeting approach designed to overcome proteolytic shedding of MICA/B by cancer cells as a means of immune cell escape. The first patient has been treated in the first three-dose escalation cohort (100 million cells per dose) as monotherapy, with FT536 administered on Days 1, 8, and 15. Upon clearance of DLTs in this first dose cohort, the clinical protocol allows combination with each of five monoclonal antibodies to promote multi-antigen targeting: EGFR- and MET-targeted amivantamab; EGFR-targeted cetuximab; HER2-targeted trastuzumab; PD1-targeted pembrolizumab; and PDL1-targeted avelumab. Eligible patients may receive up to two FT536 treatment cycles, and additional FT536 treatment cycles may be administered to patients who achieve initial clinical response.
- **iPSC-derived CAR T-cell with Seven Functional Modalities for Solid Tumors Featured at ASGCT.** At the American Society of Gene and Cell Therapy (ASGCT) 25<sup>th</sup>Annual Meeting held in May, the Company unveiled the derivation of a first-of-kind, multiplexed-engineered master iPSC line incorporating seven functional elements, which was created through the integration of multiple transgenes into multiple loci at the single-cell level. CAR T cells produced from the single-cell derived, multiplexed-engineered clonal iPSC line expressed synthetic features optimized for recognizing, binding, and killing solid tumors, and showed improved anti-tumor activity *in vitro*, including resistance to a key component of the tumor-suppressive microenvironment TGF-beta.
- Expanded Collaboration with ONO to Add Second Solid Tumor Antigen Program. In the second quarter, the Company expanded its off-the-shelf, iPSC-derived, cell-based cancer immunotherapy collaboration with Ono Pharmaceutical Co., Ltd. (ONO) to add a second solid tumor antigen program as well as include the development of both CAR NK and CAR T-cell candidates. Under the original agreement entered into between the Company and ONO in September 2018, ONO has contributed novel binding domains targeting an initial solid tumor antigen, and the Company is currently conducting preclinical development of a multiplexed-engineered, iPSC-derived CAR T-cell product candidate. Upon achievement of a pre-defined preclinical milestone, ONO has an option to assume responsibility for worldwide development and commercialization, with the Company retaining joint development and commercialization rights in the United States and Europe.

#### Janssen Collaboration Highlights

- **Clinical Development Option Exercised for First Antigen Program.** In May, Janssen exercised its commercial option for an iPSC-derived CAR NK cell collaboration product targeting an antigen expressed on certain hematologic malignancies, triggering a milestone payment to the Company. The Company expects to submit its first IND application under the collaboration during the second half of 2022. Pursuant to its commercial option exercise, Janssen has an exclusive license for development and commercialization of the product candidate, and the Company is eligible to receive clinical, regulatory, and commercial milestones, plus double-digit royalties on worldwide commercial sales of the product candidate. In addition, the Company retains the right to elect to co-commercialize, and share equally in profits and losses, in the United States, subject to its payment of certain clinical development costs and adjustments in milestone and royalty payments.
- **Preclinical Development Ongoing for Two Additional Antigen Programs.** The Company and Janssen are also conducting preclinical development of a second iPSC-derived, CAR-targeted cell candidate for an antigen expressed on certain hematologic malignancies and a third iPSC-derived, CAR-targeted cell candidate for an antigen expressed on solid tumors. In addition, during the second quarter, Janssen selected a solid tumor-associated antigen as its fourth and final program for initiation of candidate development.

#### Second Quarter 2022 Financial Results

- Cash & Investment Position: Cash, cash equivalents and investments as of June 30, 2022 were \$580.8 million.
- **Total Revenue:** Revenue was \$18.5 million for the second quarter of 2022, which was derived from the Company's collaborations with Janssen and ONO.
- **R&D Expenses:** Research and development expenses were \$81.3 million for the second quarter of 2022, which includes \$13.6 million of non-cash stock-based compensation expense.
- **G&A Expenses:** General and administrative expenses were \$20.4 million for the second quarter of 2022, which includes \$7.0 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 96.9 million, and preferred shares outstanding were 2.8 million, as of June 30, 2022. Each preferred share is convertible into five common shares.

#### **Today's Conference Call and Webcast**

The Company will conduct a conference call today, Wednesday, August 3, 2022 at 5:00 p.m. ET to review financial and operating results for the quarter ended June 30, 2022. In order to participate in the conference call, please dial (877) 545-0320 (domestic) or (973) 528-0002 (international) and refer to conference ID 687045. The live webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

#### 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 FT516

FT516 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered to express a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies. CD16 mediates antibody-dependent cellular cytotoxicity (ADCC), a potent anti-tumor mechanism by which NK cells recognize, bind and kill antibody-coated cancer cells. ADCC is dependent on NK cells maintaining stable and effective expression of CD16, which has been shown to undergo considerable down-regulation in cancer patients. In addition, CD16 occurs in two variants, 158V or 158F, that elicit high or low binding affinity, respectively, to the Fc domain of therapeutic antibodies. Numerous clinical studies with FDA-approved tumor-targeting antibodies, including rituximab, trastuzumab and cetuximab, have demonstrated that patients homozygous for the 158V variant, which is present in only about 15% of patients, have improved clinical outcomes. FT516 is being investigated in a multi-dose Phase 1 clinical trial as a monotherapy for the treatment of relapsed / refractory acute myeloid leukemia and in combination with CD20-targeted monoclonal antibodies for the treatment of relapsed / refractory B-cell lymphoma (NCT04023071).

#### About FT596

FT596 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with three anti-tumor functional modalities: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that targets B-cell antigen CD19; a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; and an IL-15 receptor fusion (IL-15RF) that augments NK cell activity. In preclinical studies of FT596, the Company has demonstrated that dual activation of the CAR19 and hnCD16 targeting receptors enhances cytotoxic activity and prevents antigen escape, indicating that multi-antigen engagement may elicit a deeper and more durable response. Additionally, in a humanized mouse model of lymphoma, FT596 in combination with the anti-CD20 monoclonal antibody rituximab showed enhanced killing of tumor cells *in vivo* as compared to rituximab alone. FT596 is

being investigated in a multicenter Phase 1 clinical trial for the treatment of relapsed / refractory B-cell lymphoma as a monotherapy and in combination with rituximab, and for the treatment of relapsed / refractory chronic lymphocytic leukemia (CLL) as a monotherapy and in combination with obinutuzumab (NCT04245722).

#### About FT819

FT819 is an investigational, universal, off-the-shelf, T-cell receptor (TCR)-less CD19 chimeric antigen receptor (CAR) T-cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line, which is engineered with the following features designed to improve the safety and efficacy of CAR19 T-cell therapy: a novel 1XX CAR signaling domain, which has been shown to extend T-cell effector function without eliciting exhaustion; integration of the CAR19 transgene directly into the T-cell receptor alpha constant (TRAC) locus, which has been shown to promote uniform CAR19 expression and enhanced T-cell potency; and complete bi-allelic disruption of TCR expression for the prevention of graft-versus-host disease. FT819 demonstrated antigen-specific cytolytic activity *in vitro* against CD19-expressing leukemia and lymphoma cell lines comparable to that of primary CAR T cells, and persisted and maintained tumor clearance in the bone marrow in an *in vivo* disseminated xenograft model of lymphoblastic leukemia. FT819 is being investigated in a multicenter Phase 1 clinical trial for the treatment of relapsed / refractory B-cell malignancies, including B-cell lymphoma, chronic lymphocytic leukemia, and acute lymphoblastic leukemia (NCT04629729).

#### About FT538

FT538 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with three functional components: a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; an IL-15 receptor fusion (IL-15RF) that augments NK cell activity; and the deletion of the CD38 gene (CD38KO), which promotes persistence and function in high oxidative stress environments. FT538 is designed to enhance innate immunity in cancer patients, where endogenous NK cells are typically diminished in both number and function due to prior treatment regimens and tumor suppressive mechanisms. In preclinical studies, FT538 has shown superior NK cell effector function, as compared to peripheral blood NK cells, with the potential to confer significant anti-tumor activity to patients through multiple mechanisms of action. FT538 is being investigated in a multi-dose Phase 1 clinical trial for the treatment of acute myeloid leukemia (AML) and in combination with daratumumab, a CD38-targeted monoclonal antibody therapy, for the treatment of multiple myeloma (NCT04614636). FT538 is also being investigated in a multi-dose Phase 1 clinical trial in combination with one of an array of tumor-targeting monoclonal antibodies for the treatment of advanced solid tumors (NCT05069935).

#### About FT576

FT576 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with four functional components: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that targets B-cell maturation antigen (BCMA); a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its down-regulation and to enhance its binding to tumor-targeting antibodies; an IL-15 receptor fusion (IL-15RF) that augments NK cell activity; and the deletion of the CD38 gene (CD38KO), which

promotes persistence and function in high oxidative stress environments. In preclinical studies, FT576 has demonstrated that the high-avidity binding of the BCMA-targeted CAR construct enables sustained tumor control against various multiple myeloma cell lines, including in long-term *in vivo* xenograft mouse models. Additionally, in combination with daratumumab, FT576 has shown complete tumor clearance and improved survival compared to primary BCMA-targeted CAR T cells in a disseminated xenograft model of multiple myeloma. FT576 is being investigated in a multicenter Phase 1 clinical trial for the treatment of relapsed / refractory multiple myeloma as a monotherapy and in combination with daratumumab (NCT05182073).

#### About FT536

FT536 is an investigational, universal, off-the-shelf natural killer (NK) cell cancer immunotherapy derived from a clonal master induced pluripotent stem cell (iPSC) line engineered with four functional components: a proprietary chimeric antigen receptor (CAR) optimized for NK cell biology that uniquely targets the alpha-3 domains of the major histocompatibility complex (MHC) class I related proteins A (MICA) and B (MICB); a novel high-affinity 158V, non-cleavable CD16 (hnCD16) Fc receptor, which has been modified to prevent its downregulation and to enhance its binding to tumor-targeting antibodies; an IL-15 receptor fusion (IL-15RF) that augments NK cell activity; and the deletion of the CD38 gene (CD38KO), which promotes persistence and function in high oxidative stress environments. High expression of MICA and MICB proteins (MICA/B), which is induced by cellular stress, damage or transformation, has been reported on many solid tumors, and while cytotoxic lymphocytes, such as NK cells and CD8+ T cells, can recognize and bind the membrane-distal alpha-1 and alpha-2 domains of MICA/B, cancer cells frequently evade immune cell recognition by proteolytic shedding of the alpha-1 and alpha-2 domains of MICA/B. Recent publications have demonstrated that antibody targeting of the MICA/B alpha-3 domains specifically prevents MICA/B shedding and restores NK cell-mediated immunity (DOI:10.1126/science.aao0505), and that cancers with B2M and JAK1 inactivating mutations resulting in loss of MHC Class I expression can be effectively targeted with MICA/B alpha-3 domain-specific antibodies to restore NK cell-mediated immunity against solid tumors resistant to cytotoxic T cells (DOI: 10.1158/2326-6066.CIR-19-0483). In preclinical studies, FT536 has been shown to elicit innate cytotoxicity, MICA/B-specific activity against multiple solid tumor targets, and antibody cellular cytotoxicity (ADCC) in combination with tumor-targeting antibodies. FT536 is being investigated in a multi-dose Phase 1 clinical trial in combination with one of an array of tumor-targeting monoclonal antibodies for the treatment of advanced solid tumors (NCT05395052).

#### 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.

#### **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 results of operations, financial condition, anticipated operating expenses and cash runway, and sufficiency of its cash and cash equivalents to fund its operations, as well as statements regarding the advancement of and plans related to its product candidates, clinical studies and preclinical research and development programs, the Company's progress, plans and timelines for the manufacture and clinical investigation of its product candidates, including the initiation and continuation of enrollment in the Company's clinical trials, the timing for the Company's receipt and announcement of data from its clinical trials and preclinical studies, the initiation of additional clinical trials and additional dose cohorts in ongoing clinical trials of the Company's product candidates and the submission of IND applications for additional programs, the Company's development and regulatory strategy, including the Company's planned interactions with regulatory authorities, the therapeutic and market potential of the Company's product candidates, the Company's expectations regarding progress and timelines, and potential payments under its collaborations, and the objectives, plans and goals of its collaborations. 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 the Company's product candidates may not demonstrate the requisite safety or efficacy to achieve regulatory approval or to warrant further development, the risk that results observed in prior studies of the Company's product candidates, including preclinical studies and clinical trials, will not be observed in ongoing or future studies involving these product candidates, the risk of a delay or difficulties in the manufacturing of the Company's product candidates or in the initiation and conduct of, or enrollment of patients in, any clinical studies, the risk that the Company may cease or delay preclinical or clinical development of any of its product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities on the initiation or conduct of clinical trials, changes in the therapeutic, regulatory, or competitive landscape for which the Company's product candidates are being developed, the amount and type of data to be generated, or otherwise to support regulatory approval, difficulties or delays in patient enrollment and continuation in the Company's ongoing and planned clinical trials, difficulties in manufacturing or supplying the Company's product candidates for clinical testing, and any adverse events or other negative results that may be observed during preclinical or clinical development), risks related to the impact of the ongoing COVID-19 pandemic on various aspects of the Company's business and operations, including its ability to initiate, conduct and complete its clinical trials, and the risk that the Company's expenditures may exceed current expectations for a variety of reasons. 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.

#### Availability of Other Information about Fate Therapeutics, Inc.

Investors and others should note that the Company routinely communicates with investors and the public using its website (www.fatetherapeutics.com) and its investor relations website (ir.fatetherapeutics.com) including, without limitation, through the posting of investor presentations, SEC filings, press releases, public conference calls and webcasts on these websites. The information posted on these websites could be deemed to be material information. As a result, investors, the media, and others interested in Fate Therapeutics are encouraged to review this information on a regular basis. The contents of the Company's website, or any other website that may be accessed from the Company's website, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

#### Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data) (unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,			
	2022		2021		2022		2021
Collaboration revenue	18,549	\$	13,412	\$	36,963	\$	24,552
Operating expenses:							
Research and development	81,307		48,023		153,446		92,873
General and administrative	20,351		12,168		41,093		24,668
Total operating expenses	101,658		60,191		194,539		117,541
Loss from operations	(83,109)		(46,779)		(157,576)		(92,989)
Other income (expense):							
Interest income	757		346		1,175		723
Change in fair value of stock price appreciation milestones	5,881		(8,700)		14,240		(7,956)
Other Income	366		-		366		-
Total other income (expense)	7,004		(8,354)		15,781		(7,233)
Net loss	\$ (76,105)	\$	(55,133)	\$	(141,795)	\$	(100,222)
Other comprehensive income (loss):							
Unrealized gain (loss) on available-for-sale securities, net	(531)		174		(2,619)		(156)
Comprehensive loss	\$ (76,636)	\$	(54,959)	\$	(144,414)	\$	(100,378)
Net loss per common share, basic and diluted	\$ (0.79)	\$	(0.58)	\$	(1.50)	\$	(1.07)
Weighted–average common shares used to compute basic and diluted net loss per share	96,704,413		94,326,648		96,524,968		93,881,734

#### Condensed Consolidated Balance Sheets (in thousands) (unaudited)

	June 30, 2022		December 31, 2021		
Assets					
Current assets:					
Cash and cash equivalents	\$	55,275	\$	133,583	
Accounts receivable		13,126		8,676	
Short-term investments and related maturity receivables		513,575		482,327	
Prepaid expenses and other current assets		17,181		8,826	
Total current assets		599,157		633,412	
Long-term investments		11,925		100,664	
Operating lease right-of-use assets		68,493		70,720	
Other long-term assets		127,484		116,659	
Total assets	<u>\$</u>	807,059	\$	921,455	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	48,944	\$	51,024	
Deferred revenue, current portion		33,657		21,483	
CIRM award liability, current portion		3,200		3,200	
Operating lease liabilities, current portion		5,717		5,577	
Total current liabilities		91,518		81,284	
Deferred revenue, net of current portion		17,743		27,124	
CIRM award liability, net of current portion		800		800	
Operating lease liabilities, net of current portion		106,587		109,241	
Stock price appreciation milestones, net of current portion		9,928		24,168	
Stockholders' equity		580,483		678,838	
Total liabilities and stockholders' equity	<u>\$</u>	807,059	\$	921,455	

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