

**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 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)
- 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 2.02 Results of Operations and Financial Condition.

On November 3, 2022, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 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 November 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: November 3, 2022

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



Fate Therapeutics Reports Third Quarter 2022 Financial Results and Highlights Operational Progress

FT596+R Enrollment Ongoing in Three-dose Escalation Cohort for R/R BCL; Activating Community Sites for Investigation of FT596+R-CHOP in Newly-diagnosed Patients with Aggressive BCL

Positive Feedback Received from FDA under FT516 RMAT Designation for Derivation of Clonal Engineered Master iPSC Bank and for Potential Registrational Study Design

Preclinical Data of FT555 GPRC5D-targeted CAR NK Cell Product Candidate for R/R MM under Janssen Collaboration to be Presented at ASH; Commercial Option Exercised by Janssen for Additional Product Candidate Targeting Undisclosed Hematologic Malignancy Antigen

14 Abstracts Selected for Presentation at ASH, including Interim Phase 1 Dose-escalation Data of FT576 for R/R MM and of FT819 for R/R BCL

12 Abstracts Selected for Presentation at SITC, including Interim Phase 1 Dose-escalation Data of FT536 and FT538 for Advanced Solid Tumors

San Diego, CA – November 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 third quarter ended September 30, 2022.

“We are very pleased with the positive feedback from the FDA under our FT516 RMAT designation in support of our iPSC product platform and potential registrational pathways for the treatment of relapsed / refractory aggressive lymphomas, including for patients who have previously failed CD19-targeted CAR T-cell therapy, and we look forward to engaging the FDA in the fourth quarter to discuss CMC topics in support of pivotal trial readiness,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We are also excited to present interim Phase 1 clinical data at the upcoming SITC and ASH conferences, including for our iPSC-derived CAR NK cell programs FT576 in multiple myeloma and FT536 in solid tumors as well as for the first-ever iPSC-derived CAR T-cell program FT819 in B-cell lymphoma. Finally, under our collaboration with Janssen, we are pleased to announce our first IND candidate FT555, a multiplexed-engineered, iPSC-derived CAR NK cell targeting GPRC5D for multiple myeloma, and that Janssen has also exercised its commercial option to an additional product candidate targeting an undisclosed hematologic malignancy antigen.”

B-cell Malignancy Disease Franchise

- **FT596+R Dose and Dose Schedule Optimization Ongoing for R/R BCL.** The Company’s multicenter Phase 1 study is designed to assess single-dose and multi-dose treatment schedules of FT596, its off-the-shelf, multiplexed-engineered, induced pluripotent stem cell (iPSC)-derived chimeric antigen receptor (CAR) natural killer (NK) cell product candidate targeting CD19, in combination with

rituximab (FT596+R) for the treatment of relapsed / refractory (r/r) B-cell lymphoma (BCL). Enrollment of a three-dose escalation cohort at 1.8 billion cells per dose, and of two-dose cohorts at 900 million cells per dose and at 1.8 billion cells per dose, is currently ongoing. The clinical protocol permits eligible patients to receive multiple treatment cycles.

- **Community Site Activation Ongoing for FT596+R-CHOP in First-line Aggressive BCL.** The Company is engaged with multiple community sites to initiate enrollment of its Phase 1b study of FT596 combined with R-CHOP, the standard immunochemotherapy regimen for patients with newly-diagnosed aggressive lymphomas. The study's objective is to assess the safety and activity and to inform the feasibility of developing FT596 without conditioning chemotherapy in the outpatient setting. The treatment schema includes administering up to six doses of FT596, with each dose being administered with each of six standard cycles of R-CHOP.
- **Positive Feedback Received from FDA under FT516 RMAT Designation.** Under the Regenerative Medicine Advanced Therapy (RMAT) designation granted to the Company's FT516 program, the Company engaged the U.S. Food and Drug Administration (FDA) and received positive feedback regarding its production, characterization, and release of its clonal master iPSC bank for use in the routine manufacture of drug product as well as potential registrational pathways for the treatment of patients with r/r aggressive lymphomas, including for patients who have relapsed or are refractory to FDA-approved CD19-directed CAR T-cell therapy. In addition, the Company was granted a follow-up meeting, scheduled for December, to review Chemistry, Manufacturing, and Controls (CMC) components of its iPSC product platform, including its drug product release specification. 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 expansion cohorts at 900 million cells per dose.
- **FT819 Enrollment Ongoing in Single-dose and Multi-dose Escalation Cohorts.** At the 64th American Society of Hematology (ASH) Annual Meeting and Exposition scheduled to take place December 10-13, 2022 in New Orleans, Louisiana, the Company plans to present interim Phase 1 dose-escalation data from its landmark study of FT819, the first-ever T-cell product candidate manufactured from a clonal master 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, designed to ensure complete bi-allelic disruption of T-cell receptor expression and promote uniform CAR expression. Dose escalation is ongoing in the third single-dose escalation cohort at 360 million cells and in the second three-dose escalation cohort at 60 million cells per dose for r/r BCL.

Multiple Myeloma Franchise

- **FT576 Enrollment Ongoing in Multi-dose Escalation Cohorts.** The multicenter Phase 1 study is designed to assess single-dose and multi-dose treatment schedules of FT576, the Company's multiplexed-engineered, iPSC-derived CAR NK cell product candidate targeting B-cell maturation antigen (BCMA), as monotherapy and in combination with daratumumab for the treatment of r/r multiple myeloma (MM). The Company has initiated enrollment in the two-dose escalation cohorts at 300 million cells per dose. At ASH, the Company will present interim Phase 1 data from the first and second single-dose escalation cohorts as monotherapy (100 million cells and 300 million cells, respectively) and from the first single-dose escalation cohort (100 million cells) in combination with daratumumab.
 - **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
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billion cells per dose). At ASH, the Company will present interim Phase 1 data from the first and second multi-dose escalation cohorts (100 million cells per dose and 300 million cells per dose, respectively).

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

- **FT536 Clears First Multi-dose Escalation Cohort as Monotherapy.** At the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting being held in Boston, MA, and virtually, November 8-12, 2022, the Company plans to present interim Phase 1 dose-escalation data for FT536, the Company's first CAR NK cell product candidate for the treatment of advanced solid tumors which uniquely targets the alpha-3 domains of the major histocompatibility complex (MHC) class I related proteins A (MICA) and B (MICB). The Company is currently conducting a multicenter Phase 1 study designed to assess a multi-dose, multi-cycle treatment schedule of FT536 as monotherapy and in combination with monoclonal antibody therapy. In the monotherapy regimen, no dose-limiting toxicities (DLTs) were observed in the first three-dose escalation cohort (100 million cells per dose), and enrollment is ongoing in the second three-dose escalation cohort (300 million cells per dose). In addition, the Company has now initiated enrollment of the combination regimen, which allows for administration of FT536 in 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).
 - **Initial FT538 Clinical Data in Combination with Monoclonal Antibody Therapy to be Presented at SITC.** The Company is currently conducting a multicenter Phase 1 study designed to assess a multi-dose, multi-cycle treatment schedule of FT538 in combination with anti-PD1/L1 or antibody-dependent cellular cytotoxicity (ADCC)-competent monoclonal antibody therapy in patients with advanced solid tumors. At SITC, the Company will present initial clinical data from the first eight patients treated in the first three-dose escalation cohort (100 million cells per dose) of FT538 in combination with cetuximab (n=3), trastuzumab (n=2), and avelumab (n=3). All eight patients completed at least one cycle of treatment with FT538, and no DLTs were observed.
 - **New Preclinical Candidate FT873 CAR T-cell Targeting pan-Cancer Antigen B7-H3 Unveiled.** At SITC, the Company will present preclinical data of FT873, a multiplexed-engineered, iPSC-derived CAR T-cell targeting B7 homolog 3 protein (B7-H3), a member of the B7 family of immunoregulatory proteins that is overexpressed in cancer and promotes tumor growth, metastasis, and drug resistance. The newly-disclosed product candidate for the treatment of solid tumors incorporates three functional elements into the T-cell receptor alpha constant (TRAC) locus: a novel camelid nanobody CAR targeting B7-H3, an IL7 receptor fusion protein, and a high-affinity, non-cleavable CD16 (hnCD16) Fc receptor. In addition to CAR targeting, the synthetic T-cell receptors are designed to improve fitness and to enable T cells to engage monoclonal antibodies and mediate a potent ADCC response.
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Janssen Collaboration Highlights

- **FT555 IND Candidate from GPRC5D Antigen Program for MM to be Presented at ASH.** In May, Janssen exercised its commercial option to FT555, a multiplexed-engineered, iPSC-derived CAR NK cell product candidate targeting GPRC5D, a tumor-associated orphan G-protein-coupled receptor found to be highly expressed on myeloma cells. The companies will jointly present preclinical data at ASH demonstrating that administration of FT555 resulted in robust tumor growth inhibition *in vivo* in a disseminated xenograft mouse model comprised of engrafted MM.1S cells, and that the durability of tumor growth inhibition as well as survival were further enhanced in combination with daratumumab to simultaneously co-target GPRC5D and CD38 antigens.
- **Commercial Option Exercised for Second Hematologic Malignancy Product Candidate.** In September, Janssen exercised its commercial option, subject to Hart-Scott-Rodino regulatory clearance, to a second multiplexed-engineered, iPSC-derived CAR NK cell product candidate, which targets an undisclosed antigen expressed on certain blood cancers. The Company expects to submit an IND application for the product candidate under the collaboration during the fourth quarter of 2022.
- **Preclinical Development Ongoing for Two Solid Tumor Antigen Programs.** The companies will jointly present preclinical data at SITC of an iPSC-derived CAR T-cell program targeting human kallikrein-related peptidase 2 (KLK2), an antigen with prostate-restricted expression that is maintained during prostate cancer progression. Preclinical data demonstrate that iPSC-derived CAR T cells targeting KLK2 have the potential to infiltrate the tumor mass and eliminate tumor cells in a highly-selective manner and to prolong survival in xenograft models of prostate cancer. In addition, during the third quarter, Janssen selected an undisclosed solid tumor-associated antigen as its fourth and final antigen program for initiation of product candidate development.

Third Quarter 2022 Financial Results

- **Cash & Investment Position:** Cash, cash equivalents and investments as of September 30, 2022 were \$519.1 million.
- **Total Revenue:** Revenue was \$15.0 million for the third quarter of 2022, which was derived from the Company's collaborations with Janssen and ONO.
- **R&D Expenses:** Research and development expenses were \$79.8 million for the third quarter of 2022, which includes \$12.5 million of non-cash stock-based compensation expense.
- **G&A Expenses:** General and administrative expenses were \$21.6 million for the third quarter of 2022, which includes \$7.0 million of non-cash stock-based compensation expense.
- **Shares Outstanding:** Common shares outstanding were 97.1 million, and preferred shares outstanding were 2.8 million, as of September 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, Thursday, November 3, 2022 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 30, 2022. In order to participate in the conference call, please register using the conference link [here](#). 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 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. 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	14,981	\$ 14,225	\$ 51,944	\$ 38,777
Operating expenses:				
Research and development	79,817	53,130	233,263	146,004
General and administrative	21,555	15,718	62,648	40,385
Total operating expenses	101,372	68,848	295,911	186,389
Loss from operations	(86,391)	(54,623)	(243,967)	(147,612)
Other income (expense):				
Interest income	1,787	289	2,962	1,012
Change in fair value of stock price appreciation milestones	891	11,026	15,131	3,070
Other Income	150	-	516	-
Total other income (expense)	2,828	11,315	18,609	4,082
Net loss	\$ (83,563)	\$ (43,308)	\$ (225,358)	\$ (143,530)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	128	13	(2,491)	(143)
Comprehensive loss	\$ (83,435)	\$ (43,295)	\$ (227,849)	\$ (143,673)
Net loss per common share, basic and diluted	\$ (0.86)	\$ (0.45)	\$ (2.33)	\$ (1.52)
Weighted-average common shares used to compute basic and diluted net loss per share	97,023,506	95,409,201	96,692,974	94,396,485

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,093	\$ 133,583
Accounts receivable	10,223	8,676
Short-term investments and related maturity receivables	423,043	482,327
Prepaid expenses and other current assets	19,970	8,826
Total current assets	535,329	633,412
Long-term investments	13,939	100,664
Operating lease right-of-use assets	67,378	70,720
Other long-term assets	132,703	116,659
Total assets	\$ 749,349	\$ 921,455
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 59,742	\$ 51,024
Deferred revenue, current portion	35,241	21,483
CIRM award liability, current portion	3,200	3,200
Operating lease liabilities, current portion	5,755	5,577
Total current liabilities	103,938	81,284
Deferred revenue, net of current portion	12,407	27,124
CIRM award liability, net of current portion	800	800
Operating lease liabilities, net of current portion	105,164	109,241
Stock price appreciation milestones, net of current portion	9,037	24,168
Stockholders' equity	518,003	678,838
Total liabilities and stockholders' equity	\$ 749,349	\$ 921,455

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