

**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): February 28, 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)

65-131152
(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 February 28, 2022, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2021. 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 February 28, 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: February 28, 2022

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



Fate Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Highlights Operational Progress

Enrollment Ongoing in Multi-dose, Multi-cycle Escalation Cohort of FT596+R at 900 Million Cells per Dose for R/R BCL; Interim Phase 1 Data of 16 Patients Showed 69% ORR and 56% CR in Single-dose Escalation Cohorts of FT596+R at ≥90 Million Cells

Granted RMAT Designation for FT516 in R/R DLBCL; Enrollment Ongoing in Multi-dose, Multi-cycle Expansion Cohorts at 900 Million Cells per Dose in Disease-specific Indications, including Aggressive BCL in Patients Previously Treated with Autologous CD19-targeted CAR T-cell Therapy

Initial FT819 Dose-Escalation Cohort Cleared with No DLTs for R/R BCL in Landmark Phase 1 Study of Off-the-shelf, iPSC-derived CAR T-cell Therapy

Preclinical Milestone Reached for Second Product Candidate under Janssen Collaboration

San Diego, CA – February 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 reported business highlights and financial results for the fourth quarter and full year ended December 31, 2021.

“We have begun 2022 with strong clinical and regulatory momentum driving our off-the-shelf, iPSC-derived NK cell programs in relapsed / refractory lymphoma, and look forward to working with the FDA under the Regenerative Medicine Advanced Therapy designation to accelerate therapeutic development in areas of significant unmet need, such as patients who have progressed following autologous CAR T-cell therapy, and to bringing transformative cell therapies to patients in the community setting including as part of early-line treatment,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “We maintain a strong financial position and are poised in 2022 to achieve key clinical milestones and data read-outs across our wholly-owned disease franchises, to extend our leadership in the manufacture and CMC of iPSC-derived cell therapies with the launch of our second cGMP manufacturing facility, and to bring new multiplexed-engineered NK and T-cell product candidates to patients.”

B-cell Malignancy Disease Franchise

- **FT596+R Multi-dose, Multi-cycle Escalation Cohort Enrolling at 900 Million Cells per Dose.** The first patients have been treated with a multi-dose, multi-cycle treatment schedule of FT596 in combination with rituximab (FT596+R) for relapsed / refractory (r/r) B-cell lymphoma (BCL) in the dose-escalation stage of the Company’s multi-center Phase 1 study. FT596 is being administered on Day 1 and Day 15 at 900 million cells per dose in each cycle, with the potential to dose escalate to

1.8 billion cells per dose. The Company plans to initiate multiple disease-specific, dose-expansion cohorts in the first quarter of 2022.

- **Positive Interim Phase 1 Clinical Data Reported for FT596+R Single-dose Escalation Cohorts.** At the 63rd American Society of Hematology (ASH) Annual Meeting in December, the Company presented positive interim Phase 1 clinical data from the single-dose escalation cohorts of its FT596 Phase 1 study. In the second (90 million cells; n=4), third (300 million cells; n=6), and fourth (900 million cells; n=6) single-dose escalation cohorts of FT596+R, 11 of 16 patients (69%) achieved an objective response (ORR), including nine patients (56%) who achieved a complete response (CR), on Day 29 as assessed by PET-CT scan per Lugano 2014 criteria. As of the data cutoff date of October 11, 2021, of the 10 patients in the second and third single-dose escalation cohorts, six patients responded and were evaluable for duration of response assessment. Five patients, all of whom were treated with a second FT596+R single-dose cycle, continued in ongoing response at a median follow-up of 4.6 months, including two patients in ongoing CR at 6.0 and 10.8 months; and one patient, who was treated with a second FT596+R single-dose cycle, reached six months in CR and subsequently had disease progression at 6.7 months. Treatment with FT596+R was well tolerated, with two low-grade adverse events (one Grade 1, one Grade 2) of cytokine release syndrome (CRS) and no adverse events of immune effector cell-associated neurotoxicity syndrome (ICANS) or graft-versus-host disease (GVHD).
 - **RMAT Designation Granted by FDA for FT516 in R/R DLBCL.** In December, the Company announced that the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to FT516 for the treatment of r/r diffuse large B-cell lymphoma (DLBCL). RMAT designation is designed to expedite the development and review of regenerative medicine therapies that have demonstrated the potential to address an unmet medical need based on preliminary clinical evidence, and allows for early interactions with the FDA, including to discuss efficient drug development and pathways for accelerated approval. The Company plans to discuss its manufacturing, CMC, and pivotal study design with the FDA during the first half of 2022. In its ongoing FT516 Phase 1 clinical trial, the Company is currently enrolling patients in three disease-specific expansion cohorts at 900 million cells per dose, each of which uses cyclophosphamide (Cy) and fludarabine (Flu) as conditioning chemotherapy: patients with r/r aggressive lymphomas who have previously been treated with CD19-targeted chimeric antigen receptor (CAR) T-cell therapy; patients with r/r aggressive lymphomas who are naïve to treatment with CD19-targeted CAR T-cell therapy; and patients with r/r follicular lymphoma. In addition, the Company is also enrolling patients in a fourth expansion cohort, without Cy/Flu conditioning chemotherapy, adding FT516 to rituximab plus bendamustine (R-Benda), a standard-of-care treatment regimen for BCL.
 - **Positive FT516 Interim Phase 1 Clinical Data Reported in Multi-dose, Multi-cycle Escalation Cohorts.** At the ASH Annual Meeting in December, the Company highlighted positive interim Phase 1 clinical data of FT516 in combination with rituximab from the multi-dose, multi-cycle escalation cohorts for the treatment of r/r BCL. Of the 18 patients treated at ≥ 90 million cells, 10 patients were naïve to treatment with autologous CD19-targeted CAR T-cell therapy, eight of whom achieved an ORR (80%), including five patients who achieved a CR (50%); and eight patients were previously treated with autologous CD19-targeted CAR T-cell therapy, three of whom achieved a CR (38%). All 11 responding patients continued in ongoing response at three months following initiation of treatment (61%), and eight patients continued in ongoing response (44%) at a median follow-up of 8.3 months. The multi-dose, multi-cycle treatment regimen was well tolerated, with no adverse events of CRS, ICANS, or GVHD.
 - **Initial FT819 Dose-Escalation Cohort Cleared with No DLTs for R/R BCL in Landmark Phase 1 Study of Off-the-shelf, iPSC-derived CAR T-cell Therapy.** FT819 is the first-ever T-cell therapy manufactured from a clonal master induced pluripotent stem cell (iPSC) line to undergo clinical
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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. In the first FT819 single-dose escalation cohort (90 million cells) for r/r BCL in the Company's Phase 1 study of FT819, there were no dose-limiting toxicities (DLTs) and no FT819-related Grade ≥ 3 adverse events. Enrollment is now ongoing in three treatment regimens for r/r BCL: single-dose cohort at 180 million cells; single-dose cohort at 90 million cells administered with low-dose IL-2 cytokine support; and three-dose cohort at 30 million cells per dose. In addition, enrollment is ongoing in the first single-dose escalation cohorts (90 million cells) for r/r chronic lymphocytic leukemia (CLL) and for r/r acute lymphoblastic leukemia (ALL).

AML Disease Franchise

- **Enrollment Ongoing in Two FT538 Phase 1 Clinical Trials.** The Company's Phase 1 study of FT538 as monotherapy and an investigator-initiated study of FT538 in combination with the CD38-targeted monoclonal antibody daratumumab are each currently enrolling patients in the second multi-dose escalation cohort (300 million cells per dose) for r/r acute myeloid leukemia (AML). The combination of FT538 with daratumumab is designed to exploit the product candidate's proprietary high-affinity, non-cleavable (hnCD16) receptor and CD38 knock-out (CD38KO) to recognize, bind, and kill CD38+ leukemic blasts through antibody-dependent cellular cytotoxicity (ADCC).

Multiple Myeloma Franchise

- **First Patients Treated in FT576 Phase 1 Study.** FT576 is derived from a clonal master iPSC line engineered with four functional components (CAR-BCMA + hnCD16 + IL-15RF + CD38KO) designed to enable multi-antigen targeting of myeloma cells, augment ADCC, promote NK cell activation without exogenous cytokine support, enhance NK cell persistence and prevent anti-CD38 monoclonal antibody-induced fratricide. The Company has treated the first patients in its multi-center Phase 1 clinical trial to assess single-dose and multi-dose treatment regimens of FT576 as monotherapy and in combination with daratumumab for the treatment of r/r multiple myeloma (MM).
- **Phase 1 Study of FT538+D Cleared Initial Dose-Escalation Cohort with No DLTs.** The Phase 1 clinical trial is designed to assess three once-weekly doses of FT538 in combination with daratumumab (FT538+D) for r/r MM. There were no DLTs observed in the first multi-dose escalation cohort (100 million cells per dose), and enrollment is now ongoing in the second multi-dose escalation cohort (300 million cells per dose) at eight U.S. sites.

Solid Tumor Franchise

- **First Patients Treated in Phase 1 Study of FT538 in Combination with Monoclonal Antibody Therapy.** The Company has treated the first patients in its multi-center Phase 1 clinical trial to assess the safety and activity of three once-weekly doses of FT538 in combination with monoclonal antibody therapy for advanced solid tumors. The clinical protocol includes combination with each of four monoclonal antibodies: EGFR-targeted cetuximab; HER2-targeted trastuzumab; PD1-targeted pembrolizumab; and PDL1-targeted avelumab. Each patient is eligible to receive up to two FT538 treatment cycles, and additional FT538 treatment cycles may be administered to patients that achieve initial clinical response. These off-the-shelf treatment cycles are designed to be administered in the outpatient setting.
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- **IND Allowed for FT536 CAR MICA/B-targeted NK Cell Product Candidate.** In December 2021, the FDA cleared an Investigational New Drug (IND) application for FT536, the Company's off-the-shelf, multiplexed-engineered, iPSC-derived NK cell product candidate, which incorporates a novel CAR targeting the major histocompatibility complex (MHC) class I related proteins A (MICA) and B (MICB). 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, although the proteolytic shedding of the $\alpha 1$ and $\alpha 2$ domains of MICA/B is recognized as a common tumor escape mechanism. The clonal master iPSC bank for FT536 was created from a single iPSC engineered with four functional elements, including the novel CAR which uniquely targets the $\alpha 3$ domain of MICA/B and is designed to overcome tumor escape mechanisms mediated by loss of MHC Class I expression and proteolytic shedding. The Company is preparing to initiate a multi-center Phase 1 clinical trial to assess a multi-dose, multi-cycle treatment schedule of FT536 as monotherapy and in combination with monoclonal antibody therapy for advanced solid tumors.

Other Corporate Highlights

- **Preclinical Milestone Reached for Second Product Candidate under Janssen Collaboration.** In January 2022, Janssen elected to initiate IND-enabling activities for a second iPSC-derived CAR NK cell product candidate incorporating a Janssen proprietary antigen binding domain, triggering the payment of a milestone fee to the Company under the collaboration.
- **Key Executive Promotions.** The Company promoted Yu-Waye (Wayne) Chu, M.D. to Chief Medical Officer and Jerome Bressi, Ph.D. to Senior Vice President, Regulatory Affairs and Quality Assurance. Dr. Chu joined the Company in 2019 from Genentech, where he led early clinical development of cancer agents spanning multiple therapeutic platforms, including polatuzumab vedotin (anti-CD79b antibody drug conjugate), mosunetuzumab (CD20/CD3 bispecific antibody), and tiragolumab (anti-TIGIT monoclonal antibody). Dr. Bressi joined the Company in 2018 and has played an integral role in pioneering the clinical investigation of iPSC-derived cell therapy in the United States, and leads the Company's regulatory strategies and interactions with the FDA for its iPSC product platform.

Fourth Quarter 2021 Financial Results & 2022 Guidance

- **Cash & Investment Position:** Cash, cash equivalents and investments as of December 31, 2021 were \$716.6 million. Cash use in the fourth quarter included a \$20 million milestone payment to Memorial Sloan Kettering Cancer Center associated with the treatment of the first patient with FT819.
 - **Total Revenue:** Revenue was \$17.1 million for the fourth quarter of 2021, which was derived from the Company's collaborations with Janssen and Ono Pharmaceutical.
 - **R&D Expenses:** Research and development expenses were \$69.5 million for the fourth quarter of 2021, which includes \$9.4 million of non-cash stock-based compensation expense.
 - **G&A Expenses:** General and administrative expenses were \$16.9 million for the fourth quarter of 2021, which includes \$5.2 million of non-cash stock-based compensation expense.
 - **Shares Outstanding:** Common shares outstanding were 95.7 million, and preferred shares outstanding were 2.8 million, as of December 31, 2021. Each preferred share is convertible into five common shares.
 - **2022 Guidance:** For the full year ending December 31, 2022, the Company expects its GAAP Loss from Operations to be between \$335 million to \$365 million, which loss includes stock-based compensation expense, and its cash use to be between \$290 million to \$315 million, which use
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excludes any amounts that may be received under its collaborations with Janssen and Ono in connection with the achievement of development milestones. The Company expects its cash, cash equivalents, and investments to exceed \$400 million at year-end 2022.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Monday, February 28, 2022 at 5:00 p.m. ET to review financial and operating results for the quarter and full year ended December 31, 2021. In order to participate in the conference call, please dial (877) 303-6235 (domestic) or (631) 291-4837 (international) and refer to conference ID 1888465. 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 multi-center 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 multi-center 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 in 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 multi-center Phase 1 clinical trial for the treatment of relapsed / refractory multiple myeloma as a monotherapy and in combination with daratumumab (NCT05182073).

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, 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, 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 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 or regulatory 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 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		Year Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Collaboration revenue	\$ 17,067	\$ 15,896	\$ 55,846	\$ 31,434
Operating expenses:				
Research and development	69,514	38,982	215,519	125,623
General and administrative	16,935	10,313	57,321	33,896
Total operating expenses	86,449	49,295	272,840	159,519
Loss from operations	(69,382)	(33,399)	(216,994)	(128,085)
Other income (expense):				
Interest income	297	345	1,309	2,400
Interest expense	-	-	-	-
Change in fair value of stock price appreciation milestones	464	(20,058)	3,534	(47,702)
Total other income (expense), net	761	(19,713)	4,843	(45,302)
Net loss	<u>\$ (68,621)</u>	<u>\$ (53,112)</u>	<u>\$ (212,151)</u>	<u>\$ (173,387)</u>
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities, net	(689)	(244)	(832)	48
Comprehensive loss	\$ (69,310)	\$ (53,356)	\$ (212,983)	\$ (173,339)
Net loss per common share, basic and diluted	<u>\$ (0.72)</u>	<u>\$ (0.61)</u>	<u>\$ (2.24)</u>	<u>\$ (2.10)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>95,788,351</u>	<u>87,358,287</u>	<u>94,747,311</u>	<u>82,385,319</u>

Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 133,583	\$ 167,347
Accounts receivable	8,676	5,515
Short-term investments and related maturity receivables	482,327	315,569
Prepaid expenses and other current assets	8,826	5,892
Total current assets	633,412	494,323
Long-term investments	100,664	—
Operating lease right-of-use asset	70,720	67,084
Other long-term assets	116,659	61,050
Total assets	\$ 921,455	\$ 622,457
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 51,024	\$ 21,847
Deferred revenue, current portion	21,483	21,144
CIRM award liability, current portion	3,200	3,200
Operating lease liability, current portion	5,577	3,355
Stock price appreciation milestones, current portion	—	36,018
Total current liabilities	81,284	85,564
Deferred revenue, net of current portion	27,124	46,021
CIRM award liability, net of current portion	800	800
Operating lease liability, net of current portion	109,241	93,943
Stock price appreciation milestones, net of current portion	24,168	11,684
Stockholders' equity	678,838	384,445
Total liabilities and stockholders' equity	\$ 921,455	\$ 622,457

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