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): January 3, 2023

FATE THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36076**	**65-1311552**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12278 Scripps Summit Drive **San Diego, California**	**92131**
(Address of Principal Executive Office)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 875-1800

N/A
(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, $0.001 par value	FATE	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.02 Termination of a Material Definitive Agreement.

On January 3, 2023, Fate Therapeutics, Inc. (the "Company") received notice of termination from Janssen Biotech, Inc. ("Janssen") of the Collaboration and Option Agreement dated April 2, 2020 by and between the Company and Janssen (the "Collaboration Agreement"), pursuant to which Janssen and the Company had agreed to collaborate to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer. Janssen provided notice of termination after the Company declined a proposal from Janssen for continuation of the Collaboration Agreement on revised terms. The termination will take effect on April 3, 2023.

Under the terms of the Collaboration Agreement, in connection with the termination, (i) all licenses and other rights granted to either party pursuant to the Collaboration Agreement will terminate, subject to limited exceptions set forth in the Collaboration Agreement; (ii) both parties will wind down any development, commercialization and manufacturing activities under the Collaboration Agreement; (iii) neither party will have any right to continue to develop, manufacture or commercialize any collaboration candidate or collaboration product or use the other party's materials; and (iv) neither party is restricted from independently developing, manufacturing, or commercializing any product, including any products directed to the same antigens as those of any collaboration candidate or collaboration product.

The foregoing summary is qualified in its entirety by reference to the Collaboration Agreement, a copy of which was filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On January 5, 2023, the Company announced the prioritization of its current and near-term clinical programs and development plans, including advancement of a second-generation CD19-targeted chimeric antigen receptor (CAR) natural killer (NK) cell program for hematologic malignancies and severe autoimmune disorders, its FT576 CAR NK cell program for multiple myeloma, its FT819 CAR T-cell program for B-cell lymphoma, and its FT825/ONO-8250 CAR T-cell program for solid tumors under its collaboration with ONO Pharmaceutical Co., Ltd.; and discontinuation of its FT516, FT596, FT538, and FT536 NK cell programs. The restructuring plan will result in a reduction in the Company's workforce to approximately 220 employees, and is expected to be completed during the first quarter of 2023. These changes are expected to extend the Company's cash runway through 2025.

The Company estimates that it will incur charges of approximately $15 million for severance and other employee termination-related costs in the first quarter of 2023. The estimated charges that the Company expects to incur are subject to a number of assumptions, and actual results may differ materially from these estimates. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, its workforce reduction. If the Company subsequently determines that it will incur additional significant costs associated with its workforce reduction, it will amend this Current Report on Form 8-K to disclose such information.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b)

In connection with the Company's restructuring plan and reduction to its workforce, the employment of Mark Plavsic, Ph.D., D.V.M., the Company's Chief Technical Officer, is expected to terminate effective as of March 6, 2023. In connection with the termination of his employment, Dr. Plavsic will be entitled under the Company's Severance and Change in Control Policy to: (i) acceleration of vesting of his outstanding equity awards for an additional nine months following the date of termination, (ii) a lump-sum severance payment in the amount of nine months of his current base salary and (iii) subject to his election thereof, payment by the Company of up to nine months of COBRA health benefits continuation.

The foregoing summary is qualified in its entirety by reference to the Company's Severance and Change in Control Policy, a copy of which was filed as Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 13, 2017.

Item 8.01 Other Events.

On January 5, 2023, the Company issued a press release announcing its termination of the Collaboration Agreement with Janssen, pipeline prioritization, next-generation programs, and key 2023 initiatives. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by such words as "expect," "anticipate," "intend," "estimate," and words of similar import and are based on current expectations that involve risks and uncertainties, such as the Company's plans, objectives, expectations and intentions. All statements other than historical or current facts are forward-looking statements, including, without limitation, statements about the wind-down of the Collaboration Agreement, the expected timing, magnitude and financial impact of the restructuring and workforce reduction, anticipated extension of the Company's cash runway, and the terms and conditions associated with the termination of executives and other employees. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially and adversely from those anticipated in the forward-looking statements. The statements in this Current Report on Form 8-K, including all forward-looking statements, speak only as of the date of this report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 5, 2023
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 hereunto duly authorized.

Date: January 5, 2023

Fate Therapeutics, Inc.

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

Fate Therapeutics Announces Termination of Collaboration Agreement with Janssen, Pipeline Prioritization, Next-Generation Programs, and Key 2023 Initiatives

Ended 2022 with Approximately $475 Million in Cash, Cash Equivalents & Receivables; 3-year Operational Runway Provided through Pipeline Prioritization and Expense Reduction

Advancing Second-generation CD19-targeted CAR NK Cell Program with Five Novel Synthetic Controls Designed to Increase Potency, Extend Functional Persistence, and Reduce Patient Conditioning for Treatment of Hematologic Malignancies and Severe Autoimmune Disorders; IND Submission Planned in Mid-2023 for NHL in Combination with CD20-targeted mAb; FT596 Product Candidate to be Discontinued

Ongoing Phase 1 Study of FT576 CAR NK Cell Program for MM to Accrue Patients in Higher-dose, Multi-dose Treatment Cohorts; Combination with CD38-targeted mAb Designed to Enable Dual-antigen Targeting and Mitigate Risk of Rejection by Selectively Depleting Activated Host Immune Cells

2023 IND Submission under Ono Collaboration Planned for FT825/ONO-8250 HER2-targeted CAR T-cell Product Candidate; Solid Tumor Program Incorporates Seven Novel Synthetic Controls Designed to Promote Effector Cell Function, Trafficking, and Resistance to Immunosuppressive Tumor Microenvironment

Ongoing FT819 Phase 1 Study of First-ever iPSC-derived CAR T-cell Therapy to Continue Dose and Dose Schedule Optimization for NHL; Single-dose and Novel Split-dose Treatment Schedules to Compare Pharmacokinetic, Safety, and Response Profiles

San Diego, CA – January 5, 2023 – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients with cancer and autoimmune disorders, announced today that it has declined a proposal from Janssen Biotech, Inc. ("Janssen") for continuation of the collaboration and option agreement between the parties on revised terms and conditions and, as a result, the agreement has been terminated and all collaboration activities will be wound down in the first quarter of 2023. In addition, the Company has completed a strategic review of its natural killer (NK) cell product pipeline and has elected to focus on advancing its most innovative and differentiated programs, which have a multiplexed-engineered cellular framework of novel synthetic controls designed to promote multi-antigen targeting, increase potency, extend functional persistence, and enable patient dosing with reduced conditioning chemotherapy. The Company ended the fourth quarter with approximately $475 million in cash, cash equivalents, and receivables and, based on its pipeline prioritization and expense reduction, the Company expects to have sufficient financial resources through the end of 2025 to capitalize on its iPSC-derived chimeric antigen receptor (CAR) NK and CAR T-cell programs.

“We are disappointed that we were not able to align with Janssen on their proposal for continuation of our collaboration, where two product candidates targeting high-value, clinically-validated hematology antigens were set to enter clinical development in 2023,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “As a consequence, in keeping with the Company’s commitment to develop disruptive product candidates, programs and technologies with the potential to address large, unmet clinical needs, we have prioritized our clinical programs and substantially reduced operating expenses, including taking the difficult and painful step of reducing our workforce, to ensure that we have a three-year cash runway. We are greatly saddened to move in this direction as our employees have continually demonstrated the highest level of dedication and commitment in pioneering iPSC-derived cell therapy for patients with cancer. I want to extend my deepest appreciation to all of our employees for their tremendous efforts and wish those employees who will be departing great success in the future.”

“Our second-generation CD19-targeted CAR NK cell program incorporates CD38 knock-out and can be effectively combined with B cell-targeted monoclonal antibody therapy, including those targeting CD20 and CD38, to direct a multi-antigen attack on target cells. This broadens the program’s therapeutic application to include both hematologic malignancies, including non-Hodgkin’s lymphoma and multiple myeloma, and severe autoimmune disorders, and has the potential to enable patient dosing with reduced conditioning chemotherapy. In 2023, we plan to initiate clinical development and assess the potential of this highly-differentiated program with five novel synthetic controls of cell function, rather than commit our resources to an expansive, registrational-directed effort for our FT596 program which does not benefit from certain attributes that we believe are critical for expanded disease application and broad patient reach,” continued Mr. Wolchko. “We also expect initial clinical data from high-dose, multi-dose treatment cohorts in multiple myeloma for our FT576 BCMA-targeted CAR NK cell program, which in combination with CD38-targeted monoclonal antibody therapy is designed to enable dual-antigen targeting and to extend functional persistence by selectively depleting activated host immune cells. In addition, we look forward this year to the further emergence of our iPSC-derived CAR T-cell programs for the treatment of hematologic malignancies and solid tumors. Dose and dose schedule optimization is ongoing for FT819, our first iPSC-derived CAR T-cell program, where we continue to assess single-dose and novel split-dose treatment schedules to compare pharmacokinetic, safety, and response profiles for non-Hodgkin’s lymphoma. We also plan to submit an IND application to the FDA for FT825/ONO-8250, our first multiplexed-engineered, CAR T-cell solid tumor program under our collaboration with ONO Pharmaceutical, which incorporates seven novel synthetic controls designed to overcome treatment challenges specific to solid tumors.”

NK Cell Programs

- **First IND Submission Planned in Mid-2023 for Second-generation CD19-targeted CAR NK Cell Program.** The Company has applied its unique ability to create multiplexed-engineered iPSC lines to improve upon its first-generation FT596 program, incorporating five novel synthetic controls designed to increase NK cell potency, enhance functional persistence, and reduce or eliminate the need to administer conditioning chemotherapy to patients. The additional features, including the knock-out of CD38, have the potential to significantly improve safety and clinical benefit, facilitate ease of combination with standard-of-care regimens including CD20- and CD38-targeted monoclonal antibody (mAb) therapy, and enable use in the treatment of non-Hodgkin’s lymphoma (NHL), multiple myeloma (MM), and severe autoimmune disorders. The program also incorporates the Company’s proprietary alloimmune defense receptor (ADR) technology for which the Company presented preclinical data at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022, which data indicated that ADR-armed, iPSC-derived CAR NK cells have the potential to proliferate, functionally persist, and durably kill tumor cells while resisting rejection by allo-reactive immune cells. The Company intends to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in mid-2023 to commence a Phase 1 study of its second-generation program in combination with CD20-targeted mAb therapy for the treatment of NHL, including without administration of intensive conditioning chemotherapy to patients.

- **Ongoing Phase 1 Study of FT576 BCMA-targeted CAR NK Cell Program to Accrue Higher-dose, Multi-dose Treatment Cohorts.** At the 2022 ASH Annual Meeting, the Company presented interim Phase 1 clinical data from the low-dose escalation cohorts of single-dose administration of FT576 as monotherapy and in combination with CD38-targeted mAb therapy for the treatment of MM, which showed encouraging clinical evidence of BCMA-targeted activity in heavily pre-treated patients and a favorable safety profile indicating its potential to be administered in the outpatient setting. Moreover, Phase 1 translational data from the combination arm showed that CD38-positive patient immune cells were rapidly and selectively depleted through the first month of therapy, suggesting that iPSC-derived NK cells incorporating CD38 knock-out, such as FT576, may be combined with CD38-targeted mAb therapy to promote dual-antigen targeting of plasma cells and mitigate the risk of rejection. Preclinical data published in November 2022 in the journal *Nature Communications* (Cichocki et al. 2022, 13:7341) demonstrated that, while single-dose administration of FT576 was effective at controlling tumor growth *in vivo*, deeper and more sustained anti-tumor activity was observed through multi-dose administration. Dose escalation assessing multi-dose administration of FT576 as monotherapy and in combination with CD38-targeted mAb therapy is currently ongoing at 300 million cells per dose.

T-cell Programs

- **Ongoing FT819 Phase 1 Study Assessing Single-dose and Novel Split-dose Treatment Schedules.** The landmark clinical trial, which is the first-ever clinical investigation of a T-cell product candidate manufactured from a clonal master iPSC line, is assessing conventional single-dose and novel split-dose treatment schedules of FT819 to compare pharmacokinetics, safety, and efficacy. Dose escalation is currently ongoing in a single-dose treatment regimen at 360 million cells and in a split-dose treatment regimen at 60 million cells per dose. At the 2022 ASH Annual Meeting, the Company presented interim clinical data from its ongoing Phase 1 study, which showed a favorable safety profile and demonstrated objective responses in heavily pre-treated patients with aggressive large B-cell lymphoma, including in patients who were not eligible for or had previously failed autologous CD19-targeted CAR T-cell therapy.
- **2023 IND Submission Planned for Multiplexed-engineered CAR T-cell Therapy FT825/ONO-8250.** Under the Company's collaboration with ONO Pharmaceutical Co., Ltd. (ONO), the parties are conducting IND-enabling activities for FT825/ONO-8250, a multiplexed-engineered, iPSC-derived CAR T-cell product candidate targeting human epidermal growth factor receptor 2 (HER2)-expressing solid tumors. The product candidate incorporates seven novel synthetic controls designed to enhance effector cell function and overcome unique challenges in treating solid tumors with cell-based cancer immunotherapies, including cell trafficking, tumor infiltration, and immune cell suppression in the tumor microenvironment. At the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting held in November 2022, the Company presented preclinical data of FT825/ONO-8250, which highlighted the differentiated targeting profile of the novel HER2-targeted binding domain, functional activity of its synthetic CXCR2 receptor to promote cell trafficking, its synthetic TGFb receptor to redirect immunosuppressive signals in the tumor microenvironment, and its synthetic interleukin-7 receptor fusion protein to induce T-cell activation. The parties expect to submit an IND application to the FDA in 2023 to commence a Phase 1 study of FT825/ONO-8250 for patients with HER2-positive solid tumors.

- **Preclinical Development to Focus on Multiplexed-engineered, Multi-antigen Targeted CAR T-cell Programs.** The Company's proprietary iPSC product platform enables the selective design of multiplexed-engineered, CAR T-cell product candidates which incorporate novel synthetic controls of cell function and can deliver multiple mechanisms of action. Through the application of its platform, the Company is developing multiplexed-engineered, multi-antigen targeted CAR T-cell product candidates utilizing its library of novel binding domains targeting hematologic malignancy and solid tumor antigens.

Wind Down of Janssen Collaboration

During the fourth quarter of 2022, the FDA allowed an IND application for a first collaboration product for the treatment of B-cell lymphoma, for which the Company expects to receive a $3 million milestone payment, and Janssen exercised its second commercial option for a collaboration product, for which the Company expects to receive a $10 million milestone payment. As a result of the collaboration's termination, during the first quarter of 2023, the Company will wind down its activities with Janssen, including discontinuing development of all collaboration products, at the expense of Janssen. As a result of such termination, all licenses and other rights granted pursuant to the agreement terminate; neither party has any right to continue to develop, manufacture or commercialize any collaboration product or use the other party's materials; and neither party is restricted from independently developing, manufacturing, or commercializing any product, including any product directed to any antigen targeted by a collaboration product.

3-year Operational Runway

The Company ended the fourth quarter of 2022 with unaudited cash, cash equivalents, and receivables totaling approximately $475 million. The Company is reducing its headcount to approximately 220 employees in the first quarter of 2023, and is discontinuing clinical development of its FT516 and FT538 NK cell programs in acute myeloid leukemia, its FT516 and FT596 NK cell programs in B-cell lymphoma, and its FT538 and FT536 NK cell programs in solid tumors. Based on its current operating plan, the Company expects to have sufficient financial resources to fund operations through 2025.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, multiplexed-engineered cell products that are selectively designed, incorporate novel synthetic controls of cell function, and can deliver multiple mechanisms of therapeutic importance to patients. 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 combines multiplexed-engineering of human iPSCs with single-cell selection to create clonal master iPSC lines. 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 multiplexed-engineered cell 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 to maximize patient reach. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 350 issued patents and 150 pending patent applications.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to bringing a first-in-class pipeline of induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients with cancer and autoimmune disorders. The Company has established a leadership position in creating multiplexed-engineered iPSC lines and in the manufacture and clinical development of universal, off-the-shelf cell products using its proprietary iPSC product platform. The Company's effector cell pipeline includes multiplexed-engineered, iPSC-derived natural killer (NK) cell and T-cell product candidates, which incorporate novel synthetic controls of cell function, such as chimeric antigen receptors (CARs) to target tumor-associated antigens, and are designed to deliver multiple mechanisms of therapeutic importance to patients, including in combination with well-established cancer therapies such as immune checkpoint inhibitors and monoclonal antibodies. 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 progress of and plans related to the Company’s product candidates, clinical studies and preclinical research and development programs, the therapeutic and market potential of the Company’s product candidates, the Company’s clinical and product development strategy, the Company’s expectations regarding its receipt of future payments for milestones achieved under its collaboration agreement with Janssen prior to the termination of the agreement, and the anticipated effects of the Company’s workforce reduction and reprioritization of preclinical and clinical development activities, including its projected cash runway. 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 warrant further development or to achieve regulatory approval, 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 trials, 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), the risk that results observed in preclinical studies of its product candidates may not be replicated in ongoing or future clinical trials, the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects, the risk that the Company may not comply with its obligations under and otherwise maintain its collaboration agreement with ONO Pharmaceutical, Ltd. or other parties with which the Company may enter into future collaborations on the agreed upon terms, the risk that research funding and milestone payments received by the Company under its collaborations may be less than expected, and the risk that the Company may incur operating expenses in amounts greater than anticipated. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company’s periodic filings with the Securities and Exchange Commission, including but not limited to the Company’s most recently filed periodic report, and from time to time in the Company’s press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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