

**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 27, 2024

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 Dr.
San Diego, CA
(Address of principal executive offices)

92131
(Zip Code)

(858) 875-1800
(Registrant's telephone number, including area code)

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 per share	FATE	The 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 27, 2024, J. Scott Wolchko provided notice of his resignation from his position as a director of Fate Therapeutics, Inc. (the “Company”), effective as of November 27, 2024. In addition, Mr. Wolchko will retire from his positions as President, Chief Executive Officer (“CEO”) and Chief Financial Officer of the Company (including his roles as the Company’s principal executive officer, principal financial officer and principal accounting officer), effective as of December 31, 2024. It is expected that Mr. Wolchko will continue to serve as a strategic advisor to the Company following his term as President and CEO. Mr. Wolchko’s resignation was not the result of any disagreement with the policies, procedures or practices of the Company. The Board thanks Mr. Wolchko for his years of service to the Company.

Bahram Valamehr, Ph.D., MBA will succeed Mr. Wolchko as a director and as the Company’s President and CEO (and as the Company’s principal executive officer, principal financial officer and principal accounting officer), effective as of January 1, 2025. Dr. Valamehr has served as the Company’s President, Research and Development since August 2024 and oversees all of the Company’s research and development activities. Biographical information for Dr. Valamehr is available in the Company’s Definitive Proxy Statement on Schedule 14A, filed with the Securities and Exchange Commission on April 26, 2024, and such information is incorporated herein by reference.

There are no arrangements or understandings between Dr. Valamehr and any other person pursuant to which he was selected as a director, President and CEO. Dr. Valamehr does not have any family relationships with any of the Company’s directors, executive officers, or other person nominated or chosen by the Company to become a director or executive officer. There are no transactions between Dr. Valamehr and the Company that would be required to be reported under Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosures.

On November 29, 2024, the Company issued a press release announcing Mr. Wolchko’s resignation and Dr. Valamehr’s appointment as President, CEO and a director of the Company. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”) or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 29, 2024
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: November 29, 2024

Fate Therapeutics, Inc.

By: /s/ Cindy R. Tahl

Cindy R. Tahl

Chief Legal and Compliance Officer



Fate Therapeutics Announces Leadership Transition

Bob Valamehr, Ph.D. MBA, To Become President and CEO January 1, 2025

Scott Wolchko To Retire as President and CEO after 10 years of Leadership in Pioneering iPSC-derived Cellular Immunotherapies

San Diego, CA – November 29, 2024 – Fate Therapeutics, Inc. (NASDAQ: FATE) (“Fate Therapeutics” or the “Company”), a clinical-stage biopharmaceutical company dedicated to bringing first-in-class induced pluripotent stem cell (iPSC)-derived cellular immunotherapies to patients with cancer and autoimmune disorders, today announced that Scott Wolchko, the Company’s President and CEO, will retire effective December 31, 2024. Fate’s current President of Research and Development (R&D), Bob Valamehr, Ph.D. MBA, will assume the role of President and CEO as of January 1, 2025. Fate Therapeutics will passionately continue its mission to develop novel off-the-shelf cellular immunotherapies to broadly treat patients in need.

Since 2015, Mr. Wolchko has guided the Company to become a leading biopharmaceutical company in the field of off-the-shelf natural killer (NK) cell and T-cell immunotherapies for patients with cancer and autoimmune diseases. During his tenure, the Company pioneered the development of a versatile and powerful iPSC product platform and treated over 300 patients with first-of-kind, multiplexed-engineered NK cell and T-cell product candidates. The Company’s innovative platform enables the generation of clonal master iPSC lines and the scaled manufacture of off-the-shelf product candidates uniquely designed and engineered to perform disease fighting roles. Mr. Wolchko will continue as a strategic advisor to the Company.

“I would like to thank Scott for his leadership and contributions since the Company’s founding and his vision in establishing Fate as a leader in creating multiplexed-engineered living drugs to tackle complex diseases and delivering them as safe and cost-effective medicines that are available on-demand,” said Bill Rastetter, Fate’s Chairman of the Board of Directors. “I have learned from Scott and admired his unique insights on building strategic differentiation into our product platform and product candidates.”

For nearly 15 years, Dr. Valamehr has led the development of the Company’s iPSC platform and is a leader in the field of cellular therapeutics. Under his direction, the Company has established a world class R&D organization yielding numerous high-tier journal publications, over 500 issued patents, and a pipeline of highly innovative cellular products. Dr. Valamehr’s pursuit to treat patients in need with novel cellular therapeutics includes the allowance of thirteen Investigational New Drug applications, spanning the treatment of hematological malignancies, solid tumors and autoimmune disorders.



Included in the Company's product candidate pipeline is FT819, the Company's off-the-shelf, CD19-targeted, 1XX CAR T-cell product candidate comprised of CD8 α β + T cells. FT819 is currently in an ongoing multi-center, Phase 1 clinical trial for patients with moderate-to-severe systemic lupus erythematosus (SLE) where the trial is designed to evaluate the safety, pharmacokinetics, and anti-B cell activity of FT819 (NCT06308978). The first three patients, all of whom presented with active lupus nephritis, received fludarabine-free conditioning followed by a single dose of FT819. All three patients remain on-study, and there have been no dose-limiting toxicities. (Goulding et al., American College of Rheumatology Annual Conference 2024).

"The initial data from our use of FT819, where we have observed a favorable safety profile, first in the treatment of aggressive B cell lymphoma, and now in the initial stages of our SLE clinical trial, provide support for the potential of the company's iPSC platform across different diseases", said Dr. Valamehr, "The first lupus nephritis patient treated with a single dose of FT819 and fludarabine-free conditioning has achieved drug-free clinical remission and continues free of all immunosuppressive therapy. We will continue the trial of FT819 in SLE as we gather insights to implement an approval strategy for this novel off-the-shelf cellular immunotherapy. We also continue to push forward our other clinical programs, including FT825 / ONO-8250 CAR T-cell product candidate for treatment of advanced solid tumors pursued in collaboration with our partner Ono Pharmaceutical."

About Fate Therapeutics' iPSC Product Platform

Human induced pluripotent stem cells (iPSCs) possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's proprietary iPSC product platform combines multiplexed-engineering of human iPSCs with single-cell selection to create clonal master iPSC lines. Analogous to master cell lines used to mass produce biopharmaceutical drug products such as monoclonal antibodies, the Company utilizes its clonal master iPSC lines as a starting cell source to manufacture engineered cell products which are well-defined and uniform in composition, can be stored in inventory for off-the-shelf availability, can be combined and administered with other therapies, and can potentially reach a broad patient population. As a result, the Company's platform is uniquely designed to overcome numerous limitations associated with the manufacture of cell therapies using patient- or donor-sourced cells. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 500 issued patents and 500 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 diseases. Using its proprietary iPSC product platform, the Company has established a leadership position in creating multiplexed-engineered master iPSC lines and in the manufacture and clinical development of off-the-shelf, iPSC-derived cell products. The Company's pipeline includes iPSC-derived natural killer (NK) cell and T-cell product candidates, which are selectively designed, incorporate novel synthetic controls of cell function, and are intended to deliver multiple therapeutic mechanisms to patients. 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 safety and therapeutic potential of the Company’s iPSC-derived CAR NK and T-cell product candidates, the advancement of and plans related to the Company’s product candidates, clinical studies and preclinical research and development programs, the Company’s progress, plans and timelines for the clinical investigation of its product candidates, the initiation and continuation of enrollment in the Company’s clinical trials, the initiation of additional clinical trials and additional dose cohorts in ongoing clinical trials of the Company’s product candidates, the timing and availability of data from the Company’s clinical trials, the therapeutic and market potential of the Company’s research and development programs and product candidates, the Company’s clinical and product development strategy, the Company’s expectations regarding progress, plans, and timelines, and Mr. Wolchko’s continued service as a strategic advisor to the Company. 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 research and development programs and product candidates, including those product candidates in clinical investigation, may not demonstrate the requisite safety, efficacy, or other attributes 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 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 or delays in manufacturing or supplying the Company’s product candidates for clinical testing, failure to demonstrate that a product candidate has the requisite safety, efficacy, or other attributes to warrant further development, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects. 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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