
**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): **March 17, 2014**

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36067
(Commission
File Number)

65-1311552
(I.R.S. Employer
Identification No.)

3535 General Atomics Court, Suite 200
San Diego, CA 92121
(Address of principal executive offices, including zip code)

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

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))
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Item 2.02 Results of Operations and Financial Condition.

On March 17, 2014, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2013. 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.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|------------------------------------|
| 99.1 | Press release dated March 17, 2014 |

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: March 17, 2014

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko
J. Scott Wolchko
Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|------------------------------------|
| 99.1 | Press release dated March 17, 2014 |



Fate Therapeutics Reports Fourth Quarter and Full Year 2013 Financial Results

Phase 2 PUMA Study of PROHEMA® Initiated - Interim Data Expected in 2H14

Clinical Trial of PROHEMA® in Lysosomal Storage Disorders to Begin in 2H14

Encouraging Clinical Data Published Highlighting the Potential of Ex Vivo T Cell Modulation

San Diego, CA — March 17, 2014 — Fate Therapeutics, Inc. (NASDAQ: FATE), a biopharmaceutical company engaged in the discovery and development of adult stem cell modulators to treat orphan diseases, today reported therapeutic program updates and announced financial results for the fourth quarter and year ended December 31, 2013.

“Over the next twelve months, we are well-positioned to expand our *ex vivo* modulation platform through clinical studies involving patients with a range of rare, life-threatening malignant and non-malignant diseases and disorders. In the second half of this year, we look forward to sharing interim results from our recently-launched Phase 2 PUMA study of PROHEMA® in adult patients with hematologic malignancies and to initiating a clinical trial of PROHEMA® in pediatric patients with certain forms of lysosomal storage disorders,” commented Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. “Additionally, we remain on track for initial clinical assessment of our Wnt7a protein therapeutics program for muscle regeneration in 2015 — we have initiated production cell line development for two proprietary Wnt7a protein analogs, and expanded our preclinical pharmacology assessment of these IND candidates beyond muscular dystrophy and into other muscle disorders.”

Recent Program Developments

- **Enrolled First Patient in Phase 2 PUMA Study for Hematologic Malignancies.** In March 2014, Fate initiated the “PUMA” (PROHEMA® in Umbilical cord blood transplant in Addults) study, a Phase 2 clinical trial designed to assess the efficacy and safety of PROHEMA® in a randomized, controlled setting in patients undergoing hematopoietic stem cell (HSC) transplantation for the treatment of hematologic malignancies. The PUMA study will be the first to use the Company’s new nutrient-rich media (NRM) formulation for the manufacture of PROHEMA®. In *in vivo* preclinical studies, PROHEMA® manufactured using this NRM formulation exhibited improved HSC viability and a more than two-fold improvement in HSC engraftment as compared to a standard cell processing media used previously in the clinical development of PROHEMA®. The trial is approved for conduct at ten major HSC transplant centers in the United States. Safety reviews are planned after six and 12 subjects, respectively, have been treated with PROHEMA®, and the Company intends to provide a clinical update in the second half of 2014 following the completion of these reviews. Full data on the primary efficacy endpoint are expected in mid-2015.
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- **Submitted a Clinical Protocol to FDA for Investigation of PROHEMA® in Pediatric Patients with Hematologic Malignancies.** In the first quarter of 2014, Fate formally engaged the FDA in dialogue concerning the evaluation of PROHEMA® in pediatric patients with a range of rare, life-threatening malignant and non-malignant diseases. In March 2014, Fate submitted a clinical protocol to FDA for the evaluation of PROHEMA® in pediatric patients with hematologic malignancies, and plans to amend its existing IND application for PROHEMA® in the second quarter of 2014 to commence clinical development in this pediatric patient population. Additionally, the Company plans to file an IND application in mid-2014, and to initiate a clinical trial in the second half of 2014, for the evaluation of PROHEMA® in pediatric patients with demyelinating lysosomal storage disorders (LSDs) including Hurler syndrome, Krabbe disease and certain leukodystrophies, all of which are characterized by progressive neurocognitive deterioration that cannot be addressed with enzyme replacement therapy. Scientists at the Company have demonstrated, in *in vivo* murine models of allogeneic transplant, that use of PROHEMA®, as compared to unmanipulated cord blood, led to a significant, several-fold increase both in the engraftment of donor HSCs in the brain, and in the mRNA levels of α -L-iduronidase and galactocerebrosidase, which are the enzymes deficient in patients with Hurler syndrome and Krabbe disease, respectively.
 - **Demonstrated Clinical Proof-of-Concept of Ex Vivo Modulation of T Cells.** In the first quarter of 2014, researchers affiliated with Harvard Medical School published in *Blood Cancer Journal* the results of a detailed immunological analysis of the T cell compartment from patients in the Company's previously-completed Phase 1b clinical trial of PROHEMA® in adult patients undergoing HSC transplantation for hematologic malignancy. It was found that subjects who received PROHEMA® had a two-fold increase in the percentage of naïve and early memory T cell fraction at Day 100 as compared to subjects undergoing transplant with unmanipulated cord blood. Naïve and early memory T cells are believed to play a key role in promoting immune reconstitution and viral immunity following cord blood transplantation. Consistent with these reported immunomodulatory effects, the Company released new data from the Phase 1b trial, which suggested that PROHEMA® may improve viral immunity: cytomegalovirus (CMV) reactivation occurred in only two of 12 PROHEMA® subjects (17%), with no cases of CMV disease; and no cases of Epstein-Barr virus (EBV)-associated post-transplant lymphoproliferative disorders (PTLD) were observed. These observations compare favorably to rates of CMV reactivation and EBV-associated PTLT reported in the literature of 36-56% and up to 16%, respectively.
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- **Initiated Production Cell Line Development, and Expanded Pharmacology Assessment, of Wnt7a Protein Analogs for Muscle Regeneration.** Fate continues to advance Wnt7a protein analogs for muscle regeneration through IND-enabling activities, and remains on track for initial clinical assessment in 2015. In the first quarter of 2014, the Company initiated production cell line development to support large-scale mammalian culture and cGMP manufacture. In addition, the Company has elected to expand the preclinical assessment of its Wnt7a-based muscle regeneration program to rodent models of muscle damage and trauma. In 2013, the Company reported encouraging preclinical results in the MDX mouse model of muscular dystrophy, where its proprietary Wnt7a protein analogs demonstrated a statistically significant increase of 17-19% in muscle strength at three weeks after a single intramuscular injection ($p < 0.0005$).
- **Published Proprietary Small Molecule-based Platform for Development of Human iPSC-derived Therapeutics.** In the first quarter of 2014, the journal *Stem Cell Reports* published the Company's work demonstrating the high-throughput derivation of human induced pluripotent stem cells (hiPSCs) that exhibit characteristics necessary for therapeutic application. The Company's proprietary combinations of small molecule modulators, which include ROCK, GSK3 and MEK pathway inhibitors, used in the hiPSC culture systems were found to be critical in promoting characteristics of the ground state of pluripotency, including pluripotent culture stability, homogeneity and survival. Based on its progress in developing a stable, robust and reproducible hiPSC platform, the Company is exploring potential therapeutic applications of hiPSC-derived muscle cells and hematopoietic cells.

Financial Results & Financial Guidance

- **Cash Position:** Cash and cash equivalents as of December 31, 2013 were \$54.0 million, compared to \$9.1 million as of December 31, 2012. The increase was primarily driven by net proceeds from our initial public offering (IPO) in the fourth quarter of 2013 of \$40.5 million and the raising of \$23.7 million in gross proceeds in the second and third quarters of 2013 through the issuance of convertible promissory notes, offset by our use of cash in operating activities of \$15.4 million.
 - **Revenues:** The Company did not have revenues for the fourth quarter of 2013. Total revenues for the fourth quarter of 2012 were \$0.6 million. Full year revenues for 2013 were \$1.0 million, compared to \$2.7 million for 2012.
 - **R&D Expenses:** Research and development expenses for the fourth quarter of 2013 were \$3.0 million, compared to \$3.4 million for the fourth quarter of 2012. Research and development expenses for each of full year 2013 and 2012 were \$12.0 million. The decrease in the fourth quarter of 2013 compared to the fourth quarter of 2012 was primarily due to the timing of clinical and regulatory related expenses incurred in the fourth quarter of 2012 in preparation for the commencement of clinical trials of PROHEMA[®] in 2013. Research and development expenses for the fourth quarter of 2013 and full year 2013 included stock-based compensation charges of \$0.2 million and \$0.9 million, respectively.
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- **G&A Expenses:** General and administrative expenses for the fourth quarter of 2013 were \$1.9 million, compared to \$1.3 million for the fourth quarter of 2012. General and administrative expenses for full year 2013 were \$6.6 million compared to \$4.2 million for 2012. The increase in G&A expenses was largely due to an increase in salary and stock-based compensation expense, and to incremental expenses primarily to support public company operations. General and administrative expenses for the fourth quarter of 2013 and full year 2013 included stock-based compensation charges of \$0.2 million and \$0.6 million, respectively.
 - **Other Income and (Expenses), Net:** Other income and (expenses), net, for the fourth quarter of 2013 were \$(0.8) million, compared to \$(0.1) million for the fourth quarter of 2012. Other income and (expenses), net, for full year 2013 were \$(3.2) million, compared to \$(0.7) million for 2012. Other income and (expenses), net, for the fourth quarter of 2013 and full year 2013 included a \$(0.4) million and a \$(2.4) million, respectively, non-cash charge due to an increase in the Company's exchangeable share liability resulting from an increase in the fair value of the exchangeable shares held by the former stockholders of Verio Therapeutics Inc.
 - **Common Shares Outstanding:** Common shares outstanding as of December 31, 2013 were approximately 20.4 million compared to 1.1 million as of December 31, 2012. Common shares outstanding as of December 31, 2013 reflect the impact of the Company's IPO on October 4, 2013 which included the automatic conversion of the Company's convertible preferred stock into common stock, the automatic conversion of the Company's convertible promissory notes into common stock and the issuance of common stock upon the retirement of the Company's exchangeable share liability.
 - **Financial Guidance.** Fate expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements until late 2015.
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Today's Conference Call and Webcast

In order to participate in the conference call, please dial 1-877-303-6235 (domestic) or 1-631-291-4837 (international) and refer to conference ID 11276251. The live webcast can be accessed under "Events & Presentations" in the Investors and Media 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, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of pharmacologic modulators of adult stem cells to treat orphan diseases. The Company utilizes established pharmacologic modalities, including small molecules and therapeutic proteins, and well-characterized biological mechanisms to enhance the therapeutic potential of adult stem cells. The Company has built two adult stem cell modulation platforms: a hematopoietic stem cell (HSC) modulation platform, which seeks to optimize the therapeutic potential of HSCs for treating patients with hematologic malignancies and rare genetic disorders, and a muscle satellite stem cell modulation platform, which seeks to activate the regenerative capacity of muscle for treating patients with degenerative muscle disorders. The Company is presently advancing its lead product candidate, PROHEMA[®], a pharmacologically-modulated HSC therapeutic, in Phase 2 clinical development for hematologic malignancies. Fate Therapeutics is also advancing its proprietary Wnt7a protein analogs in preclinical development for the treatment of muscular dystrophies. 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 therapeutic potential of our programs for the modulation of adult stem cells to treat orphan diseases, and our preclinical and clinical development plans, including the timing of, and our ability to conduct safety reviews of subjects in the PUMA study, and the timing and availability of both interim and full data in the trial, our ability to advance and the timing for the development of PROHEMA[®] for the treatment of pediatric patients, the ability of PROHEMA[®] to enhance, and the potential therapeutic benefits of enhancing, the survival and immunological properties of T cells, the timing of and our ability to complete cell line development of our Wnt7a protein analogs and advance a Wnt7a protein analog into clinical trials, the therapeutic potential of a Wnt7a protein analog for the treatment of muscle damage and trauma, the impact of our hiPSC platform technology, and our 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 risks that the results observed in prior clinical development may not be replicated in our PUMA trial or other subsequent clinical trials of PROHEMA[®], PROHEMA[®] may not produce the therapeutic benefits suggested by the results observed in our prior clinical development or may cause other unanticipated adverse effects in subsequent clinical trials, the risk of cessation or delay of any ongoing or planned preclinical or clinical development activities for a variety of reasons, including additional information that may be requested or additional obligations that may be imposed by the FDA as a condition to our initiation of new clinical trials or continuation of clinical trials with PROHEMA[®], any delays in enrollment of clinical trials with PROHEMA[®], any negative results following resumption of clinical trials with PROHEMA[®], any inability to complete the cell-line development, in vivo studies, and pharmacokinetic and toxicology assessments necessary to advance our Wnt7a analog program into clinical development, and any inability to develop hiPSC-derived muscle or hematopoietic cells suitable for therapeutic applications. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our 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 Form 10-K for the fourth quarter and year ended December 31, 2013, and from time to time the company's other investor communications. Fate Therapeutics is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

| | Three Months Ended December 31, | | For the Years Ended December 31, | |
|--|------------------------------------|-------------------|-------------------------------------|--------------------|
| | 2013 | 2012 | 2013 | 2012 |
| | (unaudited) | | | |
| Revenues: | | | | |
| Collaboration revenue | \$ — | \$ 193 | \$ 626 | \$ 1,268 |
| Grant revenue | — | 450 | 345 | 1,402 |
| Total revenue | — | 643 | 971 | 2,670 |
| Operating expenses: | | | | |
| Research and development | 3,031 | 3,403 | 12,007 | 11,999 |
| General and administrative | 1,871 | 1,284 | 6,639 | 4,228 |
| Total operating expenses | 4,902 | 4,687 | 18,646 | 16,227 |
| Loss from operations | (4,902) | (4,044) | (17,675) | (13,557) |
| Other income (expense): | | | | |
| Interest income | 3 | — | 6 | 1 |
| Interest expense | (378) | (113) | (796) | (487) |
| Loss on extinguishment of debt | — | — | — | (323) |
| Change in fair value of warrant liability | (29) | 2 | (8) | 37 |
| Change in fair value of exchangeable shares | (433) | — | (2,421) | 90 |
| Total other income (expense), net | (837) | (111) | (3,219) | (682) |
| Net loss and comprehensive loss | \$ (5,739) | \$ (4,155) | \$ (20,894) | \$ (14,239) |
| Net loss per common share, basic and diluted | \$ (0.29) | \$ (3.51) | \$ (3.54) | \$ (13.06) |
| Weighted-average common shares used to compute basic and diluted net loss per share | 19,717,235 | 1,183,488 | 5,896,171 | 1,090,317 |

Condensed Consolidated Balance Sheets

(in thousands)

| | December 31, 2013 | December 31, 2012 |
|--|----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 54,036 | \$ 9,087 |
| Prepaid expenses and other assets | 615 | 706 |
| Total current assets | 54,651 | 9,793 |
| Long-term assets | 932 | 1,283 |
| Total assets | <u>\$ 55,583</u> | <u>\$ 11,076</u> |
| Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit) | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 2,721 | \$ 2,268 |
| Other current liabilities | 1,879 | 2,582 |
| Total current liabilities | 4,600 | 4,850 |
| Exchangeable share liability | — | 551 |
| Other long-term liabilities | 135 | 1,974 |
| Convertible Preferred Stock | — | 56,526 |
| Stockholders' equity (deficit) | 50,848 | (52,825) |
| Total liabilities, convertible preferred stock and stockholders' equity | <u>\$ 55,583</u> | <u>\$ 11,076</u> |

Contact:

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