



March 12, 2015

## Fate Therapeutics Reports Year-End 2014 Financial Results

***Favorable Phase 2 Interim Data From Ongoing PUMA Study of PROHEMA® in Adult Hematologic Malignancies Reported in December 2014***

***PROHEMA Clinical Data in Pediatric Hematologic Malignancies and Rare Genetic Disorders Expected in 2015***

***IND for Programmed Mobilized Peripheral Blood Candidate Using Newly-Identified Dual Modulator Combination Planned in 2015***

***PD-L1 Programmed CD34+ Cellular Candidate Using Newly-Identified Triple Modulator Combination Advanced into Preclinical Investigation***

SAN DIEGO, March 12, 2015 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (Nasdaq:FATE), a biopharmaceutical company engaged in the development of programmed cellular therapeutics for the treatment of severe, life-threatening diseases, today announced its financial results for the fourth quarter and year ended December 31, 2014 and provided program updates.

"Over the past three months, we have made significant progress in demonstrating the broad therapeutic potential of our innovative *ex vivo* cell programming approach across a range of hematopoietic applications. In December 2014, we announced interim data from our Phase 2 PUMA study of PROHEMA® suggesting that the *ex vivo* programming of hematopoietic cells can drive therapeutic benefit in patients undergoing hematopoietic stem cell transplantation, and also presented preclinical data at the American Society of Hematology meeting demonstrating that a newly-identified dual modulator combination can significantly enhance the homing of CD34+ cells and the reactivity of T cells from mobilized peripheral blood. Today, we announced the identification of a triple modulator combination for programming immuno-regulatory properties, including PD-L1 expression, of CD34+ cells, which we are now advancing towards evaluation in preclinical models of inflammation and auto-immune disease," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "With this recent progress, we believe we are well positioned in 2015 to validate the disease-transforming potential of PROHEMA across a wide range of blood cancers and rare genetic disorders and to further apply our cell programming approach in optimizing the therapeutic potential of CD34+ cells and T cells."

### Recent Program Developments & Upcoming Milestones

- **Favorable Interim Data from Phase 2 PUMA Study of PROHEMA Announced.** In December 2014, the Company reported interim data from its Phase 2 PUMA study of PROHEMA, an *ex vivo* programmed hematopoietic cellular therapeutic derived from umbilical cord blood. The interim data showed that six of the nine engrafting subjects administered PROHEMA achieved early neutrophil engraftment and that the median time to achieve neutrophil engraftment was reduced by six and seven days in PROHEMA subjects receiving myeloablative or reduced-intensity conditioning, respectively, each as compared to pre-specified historical median times from multi-center reports published in the literature. The Phase 2 PUMA study is a randomized, controlled, open-label clinical trial designed to enroll 60 adult subjects undergoing double umbilical cord blood transplantation for the treatment of hematologic malignancies. The study will assess time to and incidence of neutrophil engraftment, which is required for the successful reconstitution of a patient's new blood and immune system, and other key endpoints that contribute to the overall morbidity and mortality of hematopoietic stem cell transplantation (HSCT), including time to and incidence of platelet engraftment as well as reductions of viral reactivation, serious infections and graft-versus-host disease. The Company expects to report data on the primary endpoint, which is based on the incidence of neutrophil engraftment versus the pre-specified historical median times, in the second half of 2015.
- **Clinical Data from Phase 1b PROMPT and PROVIDE Studies of PROHEMA in Pediatric Patients Expected in 2015.** Fate Therapeutics is currently initiating a clinical trial to investigate the potential of PROHEMA for cellular enzyme replacement in pediatric patients with inherited metabolic disorders. The Company's Phase 1b PROVIDE study, an open-label clinical trial designed to enroll 12 pediatric subjects undergoing single umbilical cord blood transplantation, has received IND allowance. Sixteen different types of lysosomal and peroxisomal storage diseases, such as Hurler and Hunter syndromes, Krabbe disease and various other leukodystrophies, qualify for treatment under the study's inclusion criteria. The study will include serial neuro-imaging and neuro-cognitive assessments to explore the potential of the programmed hematopoietic cells to provide long-term replacement of an otherwise deficient enzyme to the central nervous system through a process known as cross-correction. In addition, the Company has opened its Phase 1b PROMPT study, an open-label clinical trial of PROHEMA designed to enroll 18 pediatric subjects undergoing single umbilical cord blood transplantation for the treatment of blood cancers. The Company expects to report engraftment data

from both single cord pediatric studies in 2015.

- **Investigational New Drug Application for *Ex Vivo* Programmed Mobilized Peripheral Blood Candidate to be Filed in 2015.** Preclinical data presented by Company scientists at the 56<sup>th</sup> Annual Meeting and Exposition of the American Society of Hematology in December 2014 showed that the dual small molecule modulator combination of FT1050 and FT4145 enhances the biological properties and the *in vivo* therapeutic potential of mobilized peripheral blood. In preclinical studies, the programming of CD34+ cells with FT1050 and FT4145 resulted in a 60-fold increase in CXCR4 gene expression levels and a statistically significant increase in engraftment as compared to unmodulated cells; T cells programmed with FT1050 and FT4145 were found to have a 66% reduction of cell-surface protein expression of ICOS, a key T cell activation marker, and a statistically significant reduction in T cell proliferation rates relative to unmodulated cells. Collectively, these preclinical findings point to the therapeutic potential for *ex vivo* programmed hematopoietic cells to mitigate T cell mediated complications and improve outcomes in patients undergoing HSCT with mobilized peripheral blood as a cell source. Fate Therapeutics expects to submit an Investigational New Drug application in 2015 to enable the clinical evaluation of this programmed mobilized peripheral blood candidate in subjects undergoing allogeneic HSCT for the treatment of hematologic malignancies.
- **Triple Modulator Combination Identified for Programming PD-L1 Expression on CD34+ Cells.** Through internal research efforts, Fate Therapeutics has identified a novel combination of pharmacologic modulators that synergizes to program supra-physiologic expression levels of PD-L1, a key immunosuppressive protein, on human CD34+ cells. In recent years, the PD-1/PD-L1 pathway has been clinically validated as a promising therapeutic target. Cancer cells often exhibit high expression levels of PD-L1 in the tumor microenvironment to evade the body's immune response, and data from large clinical trials of PD-1 checkpoint inhibitors provide support for the potent immunosuppressive potential of PD-L1 expression. The Company believes that CD34+ cells with pharmacologically enhanced immunoregulatory properties hold promise as a novel therapeutic approach for treating a range of inflammatory and auto-immune diseases. Using a novel combination of three modulators, Company scientists have achieved a greater than 100-fold upregulation of PD-L1 gene expression on CD34+ cells during a 24 hour *ex vivo* treatment. *In vitro* experiments have shown that CD34+ cells programmed with the triple modulator combination significantly reduce the proliferation rates of activated T cells, as compared to unmodulated CD34+ cells. The Company is currently investigating the *in vivo* therapeutic potential of PD-L1 programmed CD34+ cells to preferentially home to sites of inflammation and to suppress T cell proliferation and cytokine production in various preclinical models of inflammation and auto-immune disease.
- **Five Newly-Issued Patents Further Bolster the Company's Induced Pluripotent Stem Cell (iPSC)-Derived Research Programs.** During the past three months, four U.S. patents that are exclusively licensed for all therapeutic purposes by Fate Therapeutics from the Whitehead Institute for Biomedical Research have been issued by the U.S. Patent and Trademark Office. These patents, Patent Nos. 8,927,279, 8,932,856, 8,940,536 and 8,951,797, have a priority date of November 2003, and cover foundational compositions and methods relating to Oct4 and its use in the generation of induced pluripotent stem cells (iPSCs). Oct4 is the key pluripotency gene, and the expression of Oct4 is required for the generation of human iPSCs. Additionally, U.S. Patent No. 8,906,677, which is exclusively licensed for all therapeutic purposes by Fate Therapeutics from The Scripps Research Institute, has also issued, and covers a small molecule-enhanced culture of human pluripotent cells that the Company believes is a required component for the efficient generation of clinical-grade iPSCs. Differentiation of iPSCs to therapeutic cells in the hematopoietic lineage, such as CD34+ cells, T cells and natural killer (NK) cells, holds promise as a potentially disruptive approach for developing next generation cellular therapeutics, including genetically engineered hematopoietic cellular therapeutics. Fate Therapeutics is currently applying its iPSC technology to research and develop iPSC-derived hematopoietic cellular therapeutics.

## Financial Results & Financial Guidance

- **Cash Position:** Cash and cash equivalents as of December 31, 2014 were \$49.1 million, compared to \$54.0 million as of December 31, 2013. The decrease is primarily driven by the Company's use of cash to fund operating activities of \$22.4 million during 2014, which was offset by proceeds from the Company's debt financing activities with Silicon Valley Bank (SVB) during the third and fourth quarter of 2014. SVB made loans to the Company in an aggregate principal amount of \$20 million, of which \$10 million was accessed in the third quarter of 2014 and the remaining \$10 million was accessed in the fourth quarter of 2014.
- **Total Operating Expenses:** Total operating expenses were \$5.9 million for the fourth quarter of 2014 and \$24.9 million for the year ended December 31, 2014, compared to \$4.9 million and \$18.6 million in the comparable periods in 2013. Operating expenses for the fourth quarter of 2014 include \$0.6 million of stock compensation expense, compared to \$0.4 million for the fourth quarter of 2013.
- **R&D Expenses:** Research and development expenses were \$3.9 million for the fourth quarter of 2014 and \$16.4 million for the year ended December 31, 2014, compared to \$3.0 million and \$12.0 million in the comparable periods in 2013. The increase in R&D expenses is primarily related to additional headcount and costs associated with the Company's conduct of its PUMA study and preparation for and the commencement of its PROMPT and PROVIDE studies.
- **G&A Expenses:** General and administrative expenses were \$2.1 million for the fourth quarter of 2014 and \$8.5 million in the year ended December 31, 2014, compared to \$1.9 million and \$6.6 million in the comparable periods in 2013. The increase in G&A expenses was largely due to incremental expenses, including from the hiring of additional headcount, to

support public company operations.

- **Common Shares Outstanding:** Common shares outstanding as of December 31, 2014 were 20.6 million, compared to 20.4 million as of December 31, 2013. Common shares outstanding as of both dates 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:** The Company expects that its existing cash and cash equivalents will be sufficient to fund its operations at least through the first quarter of 2016.

## Today's Conference Call and Webcast

The Company will conduct a conference call on Thursday, March 12<sup>th</sup>, 2015 at 5:00 p.m. EDT to report on the Company's financial and operating results for the quarter and year ended December 31<sup>st</sup>, 2014 and to provide a corporate update. 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 1392388. The live webcast can be accessed under "Events & Presentations" in the Investors and Media section of the Company's website at [www.fatetherapeutics.com](http://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 development of programmed cellular therapeutics for the treatment of severe, life-threatening diseases. The Company's approach utilizes established pharmacologic modalities, such as small molecules, to program the fate and function of cells *ex vivo*. The Company's lead product candidate, PROHEMA®, is an *ex vivo* programmed hematopoietic cellular therapeutic, which is currently in clinical development for the treatment of hematologic malignancies and rare genetic disorders in patients undergoing hematopoietic stem cell transplantation (HSCT). The Company is also using its proprietary induced pluripotent stem cell platform to develop *ex vivo* reprogrammed hematopoietic and myogenic cellular therapeutics. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit [www.fatetherapeutics.com](http://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 PROHEMA® and programmed mobilized peripheral blood, the Company's plans with respect to PROHEMA and other product candidates, anticipated clinical and development milestones (including the timing and results of ongoing and planned clinical trials, and the availability of clinical data and results), the plans of the Company to undertake certain research and development activities, including the evaluation of the *ex vivo* programming of CD34+ cells and T cells, and the Company's expected 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 of PROHEMA observed in prior preclinical and clinical development may not be replicated in current or subsequent clinical trials of PROHEMA, the risk of cessation or delay of any 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, any difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse effects or events or other negative results that may be observed in these trials), or the risk that we are unable to conduct or complete preclinical and clinical activities necessary to advance any additional hematopoietic cellular therapeutic product candidates, including any candidates derived from mobilized peripheral blood, CD34+ cells or T cells. 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 year ended December 31<sup>st</sup>, 2014, and from time to time the Company's 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 we routinely communicate with our investors and the public using our company website ([www.fatetherapeutics.com](http://www.fatetherapeutics.com)) and our investor relations website ([ir.fatetherapeutics.com](http://ir.fatetherapeutics.com)), including without limitation, through the posting of investor presentations, Securities and Exchange Commission filings, press releases, public conference calls and webcasts on our websites. The information that we post on these websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Fate Therapeutics to review the information that we post on these websites on a regular basis. The contents of our website, or any other website that may be accessed from our 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)

	Three Months Ended December 31,		For Year Ended December 31,	
	2014	2013	2014	2013
	(unaudited)			
Revenues:				
Collaboration revenue	\$ —	\$ —	\$ —	\$ 626
Grant revenue	—	—	—	345
Total revenue	—	—	—	971
Operating expenses:				
Research and development	3,865	3,031	16,435	12,007
General and administrative	2,078	1,871	8,469	6,639
Total operating expenses	5,943	4,902	24,904	18,646
Loss from operations	(5,943)	(4,902)	(24,904)	(17,675)
Other income (expense):				
Interest income	1	3	2	6
Interest expense	(291)	(378)	(549)	(796)
Loss on extinguishment of debt	—	—	(432)	—
Change in fair value of exchangeable shares	—	(433)	—	(2,421)
Change in fair value of warrant liability	—	(29)	—	(8)
Total other expense, net	(290)	(837)	(979)	(3,219)
Net loss and comprehensive loss	\$ (6,233)	\$ (5,739)	\$ (25,883)	\$ (20,894)
Net loss per common share, basic and diluted	\$ (0.30)	\$ (0.29)	\$ (1.27)	\$ (3.54)
Weighted-average common shares used to compute basic and diluted net loss per share	20,501,713	19,717,235	20,451,840	5,896,171

**Condensed Consolidated Balance Sheets**  
(in thousands)

	December 31, December 31,	
	2014	2013
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 49,101	\$ 54,036
Prepaid expenses and other assets	771	615
Total current assets	49,872	54,651
Long-term assets	1,332	932
Total assets	\$ 51,204	\$ 55,583
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,905	\$ 2,721
Long-term debt, current portion	1,546	1,732
Other current liabilities	130	147

Total current liabilities	4,581	4,600
Long-term debt, less current portion	18,083	—
Other long-term liabilities	200	135
Stockholders' equity	<u>28,340</u>	<u>50,848</u>
Total liabilities and stockholders' equity	<u><u>\$ 51,204</u></u>	<u><u>\$ 55,583</u></u>

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