

## **Fate Therapeutics Reports First Quarter 2014 Financial Results**

Phase 2 PUMA Study of PROHEMA® in Adult Hematologic Malignancies Enrolling Patients

Phase 1b PROMPT Study of PROHEMA in Pediatric Hematologic Malignancies Cleared by FDA

IND Submission for Study of PROHEMA in Rare Genetic Disorders Expected in 2Q14

SAN DIEGO, May 13, 2014 (GLOBE NEWSWIRE) -- 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 clinical development updates and announced financial results for the first quarter ended March 31, 2014.

"With the commencement of enrollment in our Phase 2 PUMA study in adults, and the FDA clearance of our investigational new drug (IND) application amendment to initiate our Phase 1b PROMPT study in pediatric patients, our clinical development of PROHEMA has progressed significantly during 2014. We are well-positioned to efficiently advance PROHEMA for the treatment of hematologic malignancies in patients across a wide range of ages, and we remain on track to complete the planned interim analysis of the PUMA study in the second half of 2014," commented Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "Additionally, our plans to expand our *ex vivo* hematopoietic stem cell (HSC) modulation platform beyond hematologic malignancies into the area of rare genetic disorders are accelerating. We now intend to submit an IND application in the second quarter of 2014 to pursue clinical development of PROHEMA in pediatric patients with inherited metabolic disorders, including various lysosomal storage disorders."

Fate Therapeutics is advancing its *ex vivo* HSC modulation platform to develop pharmacologically optimized hematopoietic stem cell therapeutics. The Company has made significant progress during 2014 in the clinical development of its first product candidate, PROHEMA, for the treatment of life-threatening malignant and rare genetic disorders.

#### **Recent Program Developments**

- Ongoing Enrollment in PUMA Study in Adult Hematologic Malignancies. In March 2014, enrollment commenced in the Phase 2 PUMA study of PROHEMA in adult patients undergoing double cord blood transplantation for the treatment of hematologic malignancies. Safety reviews are planned after six and 12 subjects, respectively, have been treated with PROHEMA, and the Company intends to provide a clinical update following the completion of these reviews, which is expected in the second half of 2014. Full data on the primary efficacy endpoint are expected in mid-2015.
- Obtained FDA Clearance to Start PROMPT Study in Pediatric Hematologic Malignancies. In April 2014, the FDA cleared an amendment to the existing PROHEMA IND, enabling the Company to initiate clinical development for the first time in pediatric patients, including children as young as one year of age. Fate plans to initiate the PROMPT study, a Phase 1b clinical trial of PROHEMA in pediatric patients with hematologic malignancies, in mid-2014. The Phase 1b PROMPT study is designed to enroll up to 18 patients undergoing single-cord blood transplantation at three leading U.S. pediatric transplant centers.
- Accelerated Plans for Clinical Development in Rare Genetic Disorders. Fate has engaged the FDA in dialogue regarding its intent to clinically investigate PROHEMA in pediatric patients with certain rare genetic disorders. Based on these communications, the Company intends to submit an IND application in the second quarter of 2014 to commence an initial clinical trial of PROHEMA in pediatric patients undergoing cord blood transplantation for the treatment of certain inherited metabolic disorders such as Hurler syndrome, Krabbe disease and various leukodystrophies. 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 increase both in the engraftment of donor HSCs and the donor-derived expression of enzymes in the brain.

#### **Financial Results & Financial Guidance**

- Cash Position: Cash and cash equivalents as of March 31, 2014 were \$47.9 million, compared to \$54.0 million as of December 31, 2013. The decrease was primarily driven by our use of cash in operating activities of \$5.3 million.
- Revenues: The Company did not have revenues for the first quarter of 2014. Total revenues for the first quarter of 2013 were \$0.5 million.
- **Total Operating Expenses:** Total operating expenses for the first quarter of 2014 were \$6.9 million, compared to \$3.8 million for the first quarter of 2013. Operating expenses for the first quarter of 2014 include \$0.9 million of stock compensation expense, compared to \$0.1 million for the first quarter of 2013, and a \$0.4 million non-cash equity charge

related to the achievement of a pre-clinical milestone pursuant to our April 2010 asset acquisition agreement with Verio Therapeutics.

- **R&D Expenses:** Research and development expenses for the first quarter of 2014 were \$4.5 million, compared to \$2.5 million for the first quarter of 2013. The increase in the first quarter of 2014 compared to the first quarter of 2013 was primarily due to both an increase in compensation and benefits expense, including stock-based compensation expense, and professional consultant and service provider expenses related to the commencement of our PUMA study in March 2014. Research and development expenses for the first quarter of 2014 included a stock-based compensation charge of \$0.6 million as well as the \$0.4 million non-cash equity charge.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2014 were \$2.4 million, compared to \$1.3 million for the first quarter of 2013. The increase in G&A expenses was largely due to both an increase in compensation and benefits expense, including stock-based compensation expense, and professional fees and insurance costs primarily to support public company operations. General and administrative expenses for the first quarter of 2014 included a stock-based compensation charge of \$0.3 million.
- Common Shares Outstanding: Common shares outstanding as of March 31, 2014 were 20.5 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.** 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.

#### **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 35782307. The live webcast can be accessed under "Events & Presentations" in the Investors and Media section of the Company's website at <a href="https://www.fatetherapeutics.com">www.fatetherapeutics.com</a>. 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 <sup>®</sup>, 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 <a href="https://www.fatetherapeutics.com">www.fatetherapeutics.com</a>.

### **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 PUMA study, our ability to advance and the timing for the development of PROHEMA for the treatment of pediatric patients, 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 study, the PROMPT study or other subsequent clinical trials of PROHEMA, PROHEMA may not produce the therapeutic benefits suggested by the results observed in preclinical investigation or our prior clinical development, or may cause other unanticipated adverse effects in subsequent clinical trials, and 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 or any delays in enrollment of or negative results in clinical trials with PROHEMA. 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-Q for the first guarter ended March 31, 2014, 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

# Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

	Three Months Ended March 31,	
	2014	2013
Revenues:	(unaudited)	
Collaboration revenue	<b>\$</b> —	\$ 209
Grant revenue	Ψ—	263
Total revenue		472
	_	412
Operating expenses:	4.500	0.504
Research and development	4,522	2,531
General and administrative	2,415	1,297
Total operating expenses	6,937	3,828
Loss from operations	(6,937)	(3,356)
Other income (expense):		
Interest income	_	1
Interest expense	(43)	(100)
Change in fair value of warrant liability	_	12
Change in fair value of exchangeable shares		(105)
Total other expense, net	(43)	(192)
Net loss and comprehensive loss	\$ (6,980)	\$ (3,548)
Net loss per common share, basic and diluted	\$ (0.34)	\$ (2.92)
Weighted-average common shares used to compute basic and diluted net loss per share	20,346,856	1,213,286

# Condensed Consolidated Balance Sheets (in thousands)

	March 31, December 31,		
	2014	2013	
Assets	(unaudited)		
Current assets:			
Cash and cash equivalents	\$ 47,881	\$ 54,036	
Prepaid expenses and other assets	382	615	
Total current assets	48,263	54,651	
Long-term assets	1,386	932	
Total assets	\$ 49,649	\$ 55,583	
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable and accrued expenses	\$ 2,971	\$ 2,721	
Other current liabilities	1,383	1,879	
Total current liabilities	4,354	4,600	
Other long-term liabilities	118	135	
Stockholders' equity	45,177	50,848	

Total liabilities and stockholders' equity

\$ 49,649

\$ 55,583

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