

### **Fate Therapeutics Reports Second Quarter 2015 Financial Results**

Interim Data From PROHEMA® PUMA Study Show Reduction in Severe Infections Across Multiple Pathogen Types

First Pediatric Subject Treated in PROHEMA® PROVIDE Study of CNS Cellular Replacement

Strategic Research Collaboration Formed With Juno Therapeutics to Identify Small Molecule Modulators for Programming CAR T and TCR Immunotherapeutics

Two Natural Killer Cell-Based Programs Launched in Collaboration With University of Minnesota for Development of "Off-the-Shelf" Cancer Immunotherapeutics

SAN DIEGO, Aug. 5, 2015 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company engaged in the development of programmed cellular immunotherapeutics for the treatment of severe, life-threatening diseases, today announced its financial results for the second quarter ended June 30, 2015, and recent corporate and clinical highlights.

"The interim data from our Phase 2 PUMA study indicate that the therapeutic value proposition of PROHEMA may include the prevention of severe life-threatening infections across a broad spectrum of bacterial, fungal and viral pathogens through a one-time administration at the time of hematopoietic cell transplantation (HCT). This would alleviate a significant cause of morbidity and mortality in patients undergoing HCT and also reduce the need for costly anti-infective treatment regimens following HCT," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "During the second half of 2015, we look forward to sharing additional clinical data from our adult and pediatric clinical development initiatives for PROHEMA. Additionally, we are aggressively moving to extend the promising observations from our PROHEMA clinical experience to other cell sources used in HCT including mobilized peripheral blood, where severe infections and graft-versus-host disease represent significant unmet medical needs. We remain on track to file an IND by the end of 2015 for PROTMUNE, a programmed mobilized peripheral blood immunotherapeutic designed to enhance the therapeutic properties of donor T cells."

#### **Recent Corporate & Clinical Highlights**

- Encouraging Immunoprotection Data from Ongoing PUMA Study Observed. On May 6, 2015, the Company reported interim data from an initial 30 subjects in its ongoing Phase 2 PUMA study of PROHEMA, a programmed hematopoietic cell-based immunotherapeutic derived from umbilical cord blood. Immunocompromised subjects administered PROHEMA had a 54% reduction in the rate of infection-related adverse events, including severe bacterial, fungal and viral infections following HCT. Specifically, subjects administered PROHEMA experienced 0.7 total events per subject (13 total events in 18 subjects) as compared to 1.6 total events per subject in the control cohort (19 total events in 12 subjects). Importantly, the event rate for cytomegalovirus (CMV) infection was 0.0 in subjects administered PROHEMA (0 total events in 18 subjects) as compared to 0.3 in the control cohort (4 total events in 12 subjects); and the event rate for bacterial infections was 0.3 in subjects administered PROHEMA (6 total events in 18 subjects) as compared to 0.6 in the control cohort (7 total events in 12 subjects). The ongoing PUMA study, which is designed to investigate several key measures of hematopoietic reconstitution and immunoprotection in adult subjects undergoing double umbilical cord blood transplantation, is expected to enroll approximately 60 total subjects, randomized at a ratio of 2:1.
- First Subject Treated in Pediatric PROVIDE Study Assessing CNS Cellular Replacement Potential of PROHEMA. The first subject in the Company's Phase 1b PROVIDE study, an open-label clinical study of PROHEMA designed to enroll 12 pediatric subjects undergoing single umbilical cord blood transplantation for the treatment of inherited metabolic disorders, has been treated. The study's design includes serial neuro-imaging and neuro-cognitive assessments to explore the potential of programmed hematopoietic cells to durably reconstitute in the brain and deliver enzymes which are otherwise missing to the central nervous system. Multiple inherited metabolic disorders, including lysosomal and peroxisomal storage diseases such as Hurler and Hunter syndromes, Krabbe disease and other leukodystrophies, qualify for treatment under the PROVIDE study.
- IND for Programmed Mobilized Peripheral Blood Immunotherapeutic to be Filed in 2H15. The Company expects to file an Investigational New Drug application in the second half of 2015 to conduct a first-in-human clinical assessment of PROTMUNE, a programmed hematopoietic cell-based immunotherapeutic derived from mobilized peripheral blood. In preclinical models of acute graft-versus-host disease (GvHD), host mice that received programmed mobilized peripheral blood cells from a mismatched donor showed a statistically-significant (p < 0.0001) reduction in GvHD score and a

statistically-significant (p=0.0005) improvement in survival, as compared to mice that received vehicle treated cells. The Company plans to evaluate the potential of PROTMUNE to reduce life-threatening complications of allogeneic HCT, such as acute GvHD, in adult subjects undergoing mobilized peripheral blood HCT.

- Strategic Research Collaboration Formed with Juno Therapeutics to Program CAR T and TCR Immunotherapeutics. On May 4, 2015, the Company entered into a research collaboration and license agreement with Juno to identify and apply small molecule modulators to program genetically-engineered chimeric antigen receptor (CAR) T-cell and T-cell receptor (TCR) immunotherapeutics. Under the collaboration, Juno paid the Company an upfront fee of \$5.0 million, purchased one million shares of the Company's common stock at \$8.00 per share, and agreed to fund all of the Company's collaboration activities during the four-year research term. For each product developed by Juno that incorporates modulators identified through the collaboration, the Company is eligible to receive clinical, regulatory and commercial milestones, plus royalties on net sales.
- Natural Killer Cell-based "Off-the-Shelf" Cancer Immunotherapeutic Programs Launched in Collaboration with University of Minnesota. In July 2015, the Company entered into a collaboration with the University of Minnesota to clinically translate two distinct NK cell-based cancer immunotherapeutic programs, both of which seek to overcome key limitations of adoptive T-cell immunotherapy including the requirement to isolate and engineer cells for each individual patient. In the first program the Company intends to accelerate the development of an "adaptive" NK cell phenotype, which has been shown to have an epigenetic profile similar to that of cytotoxic T lymphocytes and to exhibit long-term persistence *in vivo*. The second program leverages the Company's proprietary induced pluripotent stem cell (iPSC) technology, which has the potential to enable the efficient and precise engineering of single pluripotent cells and the large-scale clonal expansion of such cells, in the development of iPSC-derived NK cell-based targeted cancer immunotherapeutics.

#### **Financial Results**

- Cash Position: Cash and cash equivalents as of June 30, 2015 were \$81.2 million, compared to \$49.1 million as of December 31, 2014. The increase is primarily driven by net proceeds from the Company's public offering of common stock in May 2015 and cash generated from entering into the strategic research collaboration with Juno, offset by cash used to fund operating activities.
- **Total Revenue:** Revenue was \$0.3 million for the second quarter of 2015, which was derived from the Company's strategic research collaboration with Juno.
- **Total Operating Expenses:** Total operating expenses were \$7.5 million for the second quarter of 2015, compared to \$6.0 million for the second quarter of 2014. Operating expenses for the second quarter of 2015 includes \$0.7 million of stock compensation expense, compared to \$0.4 million for the second quarter of 2014.
- **R&D Expenses:** Research and development expenses were \$4.9 million for the second quarter of 2015, compared to \$4.0 million for the second quarter of 2014. The increase in R&D expenses is primarily related to an increase in personnel expense, including stock-based compensation expense, resulting from additional headcount to support the clinical development of PROHEMA and the preclinical evaluation of the Company's other product candidates.
- **G&A Expenses:** General and administrative expenses were \$2.7 million for the second quarter of 2015, compared to \$2.1 million during the second quarter of 2014. The increase in G&A expenses is primarily related to an increase in personnel expense, including stock-based compensation expense, and an increase in intellectual property expenses.
- Common Shares Outstanding: Common shares outstanding as of June 30, 2015 were 28.6 million compared to 20.6 million in December 31, 2014. Common shares outstanding increased primarily as a result of the 6.9 million shares of the Company's common stock issued pursuant to the May 2015 financing, and the 1.0 million shares of the Company's common stock issued and sold to Juno pursuant to the strategic research collaboration.

#### **Today's Conference Call and Webcast**

The Company will conduct a conference call on Wednesday, August 5th, 2015 at 5:00 p.m. ET to report on the Company's financial and operating results for the quarter ended June 30th, 2015 and 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 93536859. 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 development of programmed cellular

immunotherapeutics for the treatment of severe, life-threatening diseases. The Company's lead product candidate, PROHEMA®, is a programmed hematopoietic cell-based immunotherapeutic, which is currently in clinical development in patients undergoing hematopoietic cell transplantation. The Company is also developing a PD-L1 programmed CD34+ cell immunotherapeutic for the treatment of autoimmune diseases and is leveraging its proprietary induced pluripotent stem cell platform to develop natural killer cell and T-cell cancer immunotherapeutics. 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 the Company's product candidates, including PROHEMA® and PROTMUNE™, and any product candidates that may arise from the Company's strategic collaborations with Juno Therapeutics, Inc. and the University of Minnesota, the Company's clinical development plans for PROHEMA and PROTMUNE, the timing of availability of data from the Company's ongoing Phase 2 PUMA study, the timing of the Company's filing of an IND and initiation of the clinical investigation for PROTMUNE, the success of the Company's collaborations with Juno and the University of Minnesota, and the amount and timing of potential milestone payments and royalties that the Company is eligible to receive under its strategic collaboration with Juno. 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 ongoing clinical trials, including the PUMA study and the PROVIDE study, or in subsequent clinical trials of PROHEMA, the results observed in the PUMA study to date represent only interim results for a limited number of patients and final results may differ materially, the Company may cease or delay preclinical or clinical development activities for any of its existing or future product candidates for a variety of reasons (including additional requirements that may be imposed by regulatory authorities, changes in regulatory approval pathways, difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse events or other negative results that may be observed during preclinical or clinical development), or the Company's strategic collaborations with Juno and with the University of Minnesota may not be successful or may be terminated for a variety of reasons. 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 guarter ended June 30<sup>th</sup>, 2015, 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 (<a href="www.fatetherapeutics.com">www.fatetherapeutics.com</a>) and our investor relations website (<a href="irr.fatetherapeutics.com">irr.fatetherapeutics.com</a>), 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(unaudited)			
Collaboration revenue	\$ 329	<b>\$</b> —	\$ 329	\$ <i>—</i>
Operating expenses:				
Research and development	4,857	3,968	9,425	8,490
General and administrative	2,690	2,072	5,446	4,487
Total operating expenses	7,547	6,040	14,871	12,977
Loss from operations	(7,218)	(6,040)	(14,542)	(12,977)

Other income (expense):				
Interest income	2	1	3	1
Interest expense	(563)	(28)	(1,121)	(71)
Total other expense, net	(561)	(27)	(1,118)	(70)
Net loss and comprehensive loss	\$ (7,779)	\$ (6,067)	\$ (15,660)	\$ (13,047)
Net loss per common share, basic and diluted	\$ (0.33)	\$ (0.30)	\$ (0.70)	\$ (0.64)
Weighted-average common shares used to compute basic and diluted net loss per share	23,920,630	20,467,782	22,246,832	20,407,632

# Condensed Consolidated Balance Sheets (in thousands)

	June 30,	December 31,
	2015	2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 81,176	\$ 49,101
Prepaid expenses and other assets	395	760
Total current assets	81,571	49,861
Long-term assets	1,912	1,322
Total assets	\$ 83,483	\$ 51,183
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,998	\$ 2,905
Long-term debt, current portion	5,156	1,535
Deferred revenue, current portion	2,105	_
Other current liabilities	56	130
Total current liabilities	11,315	4,570
Long-term debt, less current portion	14,539	18,073
Deferred revenue	5,986	_
Other long-term liabilities	569	200
Stockholders' equity	51,074	28,340
Total liabilities and stockholders' equity	\$ 83,483	\$ 51,183

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Source: Fate Therapeutics, Inc

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