

Fate Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results

ProTmune™ Investigational New Drug Application for Prevention of Acute GvHD and CMV Infection Cleared by FDA in January 2016

Phase 1/2 Clinical Trial of ProTmune to Commence Enrollment in mid-2016

Data Updates for All Preclinical Adoptive Immunotherapy Programs Expected in 1H16

SAN DIEGO, March 03, 2016 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2015.

"During this past year, we significantly advanced our long-term corporate strategy, successfully building a ground-breaking preclinical pipeline of programmed adoptive immunotherapies, including a NK-cell therapy for solid tumors, a CD34+ cell therapy for autoimmune diseases and off-the-shelf cancer therapies derived from engineered pluripotent cell lines. We also formed a strategic research collaboration with Juno Therapeutics, leveraging our expertise in hematopoietic cell biology and *ex vivo* cell programming, to enhance the therapeutic function of Juno's engineered T-cell immunotherapies," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We have continued this momentum into 2016, having secured FDA clearance to conduct a Phase 1/2 clinical trial of ProTmune, and we look forward to safety and efficacy data from this trial during 2016. Finally, we will begin sharing data across our entire preclinical pipeline at industry-leading scientific conferences during the first half of 2016."

Recent Highlights

- | **FDA Clearance of IND Application for ProTmune™ Phase 1/2 Study.** In January 2016, Fate Therapeutics announced that its Investigational New Drug (IND) application for ProTmune (FT1050-FT4145 programmed mobilized peripheral blood cells) was cleared by the U.S. Food and Drug Administration (FDA). The Company expects to commence enrollment of a multi-center, randomized, controlled Phase 1/2 clinical trial of ProTmune for the prevention of acute graft-versus-host disease (GvHD) and cytomegalovirus (CMV) infection in mid-2016, both of which are severe life-threatening immunological conditions with no approved FDA therapies.
- | **ProTmune Preclinical Data Highlighted at 2015 American Society of Hematology Meeting (ASH) and 2016 BMT Tandem Meetings.** Fate Therapeutics presented ProTmune preclinical data demonstrating that FT1050-FT4145 programmed immune cells reduce acute GvHD and retain anti-tumor, or graft-versus-leukemia (GvL), activity *in vivo*. Acute GvHD is a leading cause of morbidity and mortality in patients undergoing allogeneic HCT, and therapeutic strategies aimed at addressing GvHD that suppress or deplete the immune system can compromise or eliminate T cells, often leading to severe infections and disease relapse. GvL activity is critical to eradicating residual cancer and realizing the curative potential of allogeneic HCT.
- | **Pluripotent Cell Platform for Off-the-Shelf NK- and T-Cell Cancer Immunotherapies Highlighted at 2015 ASH Meeting.** Fate Therapeutics presented the Company's patent-protected, pluripotent cell platform, which combines genetic engineering of pluripotent cells with rapid and efficient generation of immune cells, for developing off-the-shelf engineered cancer immunotherapies without requiring patient-sourced cells. Highlighted features of this platform include the precise integration of multiple genetic modifications into pluripotent cells, the efficient expansion of engineered pluripotent cell clones, and the derivation of CD34+ cells, NK cells and T cells using well-defined, small molecule-driven protocols.
- | **Patent Position Covering Pluripotent Cell Platform Significantly Expanded.** In 2015, Fate Therapeutics and its exclusive licensors were granted 21 patents covering induced pluripotent cell technology, extending its formidable position to include over 60 issued patents and 90 pending patent applications. Most notably, in October 2015, the U.S. Patent and Trademark Office issued U.S. Patent No. 9,169,490 providing broad protection for cell compositions expressing a sufficient amount of octamer-binding transcription factor 4 (Oct4) to enable pluripotency. The production of Oct4 protein within a cell is critical to generate highly-stable, genetically-modified, clonal pluripotent cell lines for use in the unlimited production of off-the-shelf engineered cell therapies.

- 1 **NK- and CD34+ Cell Immunotherapy Collaborations Formed with Leading Medical Institutions.** In July 2015, Fate Therapeutics entered into a multi-year agreement with the University of Minnesota, under which the Company is advancing toward clinical development an Adaptive NK-cell cancer immunotherapy for solid tumors in collaboration with Dr. Jeffrey Miller, M.D., Professor of Medicine and Deputy Director, University of Minnesota Cancer Center. Additionally, in June 2015, the Company entered into a multi-year research agreement with Boston Children's Hospital to develop an immuno-regulatory CD34+ cell therapy, which is currently being assessed in several preclinical models of T cell-mediated immune dysfunction.
- 1 **Juno Therapeutics Strategic Research Collaboration Formed to Program T-Cell Immunotherapies.** In May 2015, the Company entered into a research collaboration and license agreement with Juno Therapeutics, Inc. to identify small molecule modulators that enhance the therapeutic function of genetically-engineered chimeric antigen receptor (CAR) T-cell and T-cell receptor (TCR) immunotherapies. 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. For the first five therapies developed by Juno that incorporate modulators identified through the collaboration, the Company is eligible to receive approximately \$500 million upon the achievement of various clinical, regulatory and commercial milestones, plus royalties on net sales.

Upcoming Anticipated Milestones

- 1 First patient to be administered ProTmune in Phase 1 stage of Phase 1/2 clinical trial in mid-2016
- 1 Adaptive NK Cell cancer immunotherapy program update (The Innate Killer Summit, May 16-18, 2016, San Diego, CA)
- 1 Programmed CD34+ Cell immuno-regulatory program update (American Diabetes Association's 76th Scientific Sessions, June 10-14, 2016, New Orleans, LA)
- 1 Off-the-Shelf, pluripotent cell-derived NK- and T-Cell cancer immunotherapy program updates (International Society for Stem Cell Research, June 22-25, 2016, San Francisco, CA)
- 1 First patient to be administered ProTmune in Phase 2 stage of Phase 1/2 clinical trial in the fourth quarter of 2016
- 1 Data update from Phase 1/2 ProTmune clinical trial (American Society of Hematology, December 3-6, 2016, San Diego, CA)

Financial Results & Guidance

- 1 **Cash Position:** Cash and cash equivalents as of December 31, 2015 were \$64.8 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 a research collaboration and license agreement with Juno Therapeutics in May 2015, offset by cash used to fund operating activities.
- 1 **Total Revenue:** Revenue was \$1.1 million for the fourth quarter of 2015 and \$2.4 million for the year ended December 31, 2015. All revenue was derived from the Company's collaboration with Juno.
- 1 **Total Operating Expenses:** Total operating expenses were \$8.0 million for the fourth quarter of 2015 and \$30.2 million for the year ended December 31, 2015, compared to \$5.9 million and \$24.9 million in the comparable periods in 2014. Operating expenses for the fourth quarter of 2015 include \$0.5 million of stock compensation expense, compared to \$0.6 million for the fourth quarter of 2014.
- 1 **R&D Expenses:** Research and development expenses were \$5.4 million for the fourth quarter of 2015 and \$19.9 million for the year ended December 31, 2015, compared to \$3.9 million and \$16.4 million in the comparable periods in 2014. The increase in R&D expenses is primarily related to an increase in third-party professional consultant and service provider fees to support the clinical development of our product candidates, and an increase in personnel expenses, including stock-based compensation expense, resulting from additional headcount to support the conduct of research activities.
- 1 **G&A Expenses:** General and administrative expenses were \$2.6 million for the fourth quarter of 2015 and \$10.4 million for the year ended December 31, 2015, compared to \$2.1 million and \$8.5 million in the comparable periods in 2014. The increase in G&A expenses is primarily related to an increase in personnel expenses, including stock-based compensation expense, and an increase in costs related to our intellectual property portfolio.

- 1 **Common Shares Outstanding:** Common shares outstanding as of December 31, 2015 were 28.7 million compared to 20.6 million as of 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 collaboration.
- 1 **Financial Guidance:** The Company expects 2016 net cash burn to be between \$38 million and \$42 million.

Today's Conference Call and Webcast

The Company will conduct a conference call on Thursday, March 3, 2016 at 5:00 p.m. ET to review financial and operating results for the quarter and full year ended December 31, 2015. 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 58417776. The live webcast can be accessed under "Events & Presentations" in the Investors & 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 ProTmune™

ProTmune™ is an investigational programmed cellular immunotherapy undergoing clinical development for use as an allogeneic HCT cell source in adult patients with hematologic malignancies. The cell therapy is produced by modulating donor-sourced, human mobilized peripheral blood (mPB) *ex vivo* with two small molecules (FT1050 and FT4145) to enhance the biological properties and therapeutic function of the hematopoietic cells. The programmed mPB cells are adoptively transferred and administered to a patient as a one-time intravenous infusion.

About Fate Therapeutics, Inc.

Fate Therapeutics is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's cell therapy pipeline is comprised of immuno-oncology programs, including off-the-shelf NK- and T-cell cancer immunotherapies derived from engineered induced pluripotent cells, and immuno-regulatory programs, including hematopoietic cell immunotherapies for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing autoimmunity. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. 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 Company's advancement of, and anticipated development and regulatory milestones and plans related to, the Company's product candidates, clinical studies and partnerships as well as the Company's projected cash expenditures. 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 results observed in prior studies, including preclinical studies of ProTmune™, will not be observed in ongoing or future studies involving these product candidates, the risk that 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 requirements that may be imposed by regulatory authorities and requirements for regulatory approval, 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), the risk that the Company's research collaborations, including with Juno Therapeutics, may not be successful or may be terminated, and the risk that the Company's expenditures may exceed current expectations 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 most recently filed quarterly report, 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) and our investor relations website (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,		Years Ended December 31,	
	2015	2014	2015	2014
	(unaudited)			
Collaboration revenue	\$ 1,076	\$ —	\$ 2,431	\$ —
Operating expenses:				
Research and development	5,433	3,865	19,861	16,435
General and administrative	2,555	2,078	10,352	8,469
Total operating expenses	7,988	5,943	30,213	24,904
Loss from operations	(6,912)	(5,943)	(27,782)	(24,904)
Other income (expense):				
Interest income	3	1	10	2
Interest expense	(537)	(291)	(2,220)	(549)
Loss on extinguishment of debt	—	—	—	(432)
Total other expense, net	(534)	(290)	(2,210)	(979)
Net loss and comprehensive loss	\$ (7,446)	\$ (6,233)	\$ (29,992)	\$ (25,883)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.30)	\$ (1.18)	\$ (1.27)
Weighted-average common shares used to compute basic and diluted net loss per share	28,687,797	20,501,713	25,484,262	20,451,840

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, December 31,	
	2015	2014
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 64,809	\$ 49,101
Prepaid expenses and other assets	843	760
Total current assets	65,652	49,861
Long-term assets	2,306	1,322
Total assets	\$ 67,958	\$ 51,183
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,435	\$ 2,905
Long-term debt, current portion	7,550	1,535
Deferred revenue, current portion	2,401	—
Other current liabilities	55	130

Total current liabilities	13,441	4,570
Long-term debt, less current portion	10,688	18,073
Deferred revenue	4,934	—
Other long-term liabilities	857	200
Stockholders' equity	38,038	28,340
Total liabilities and stockholders' equity	<u>\$ 67,958</u>	<u>\$ 51,183</u>

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