# **Fate Therapeutics**

(FATE-NASDAQ)

Stock Rating: Outperform

Stock Price: \$8.78 Target Price: \$11.00 Thursday, March 13, 2014 Biotechnology

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### Initiation of PUMA Study Sets Up Potential 2H14 Catalyst in Stem Cell Transplant

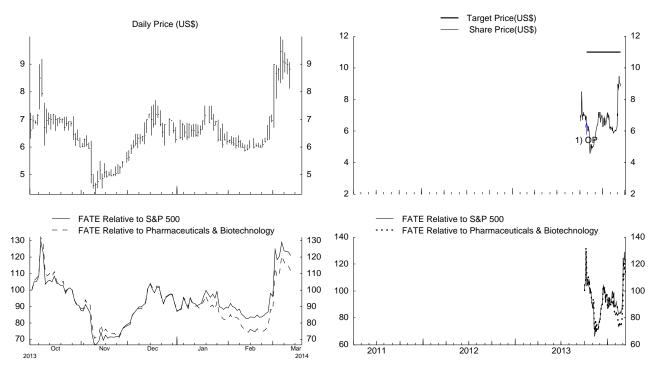
Fate Therapeutics announced yesterday the enrollment of the first patient in its PUMA phase 2 study of modulated cord blood stem cell product PROHEMA in patients undergoing hematopoietic stem cell (HSC) transplant for hematologic malignancy. The PUMA study will be conducted at 10 major transplant centers in the U.S. and is designed with interim analyses for safety after treatment of 6 and 12 patients and with full data on the primary engraftment endpoint by mid-2015. The study will enroll 60 patients, randomized 2:1 to either PROHEMA + unmanipulated cord blood unit vs. 2 unmanipulated cord blood units, following either intensive myeloablative therapy or a reduced intensity treatment regimen. The primary endpoint in the PUMA study is the cumulative incidence of time to neutrophil engraftment comparted to a prespecified control median adjusted based on median time to engraftment in the control arm. Secondary endpoints include additional measures of neutrophil and platelet engraftment, rates of graft failure, disease free- and overall survival and safety.

#### Our View:

- Initiation of the PUMA study represents a major opportunity for FATE to establish proof-of-concept for an optimized stem cell product in a high area of unmet need.
- With 20-30% rates of 100-day mortality and with significant morbidity and cost associated with delayed engraftment, we believe that any improvement in time to engraftment or reduced complications with PROHEMA would be meaningful.
- Based on prior phase 1b data demonstrating 3-4 day improvements in time to engraftment and with an improved nutrient-rich media formulation demonstrating enhanced properties of engraftment, we believe that the likelihood of success in PUMA is high.
- While final PUMA data isn't expected until mid-2015, we expect some engraftment data on the second interim safety analysis by year-end 2014, an upside opportunity to prior estimates.
- Ultimately, we expect FATE to leverage its expertise in stem cell therapeutics into PROHEMA development for rare genetic disorders like Hurler's Syndrome, into in-vivo satellite stem cell modulation in Muscular Dystrophy (DMD) and more broadly in human-induced pluripotent stem cells.

Please refer to pages 2 to 5 for Disclosure Statements, including the Analyst's Certification.

## Fate Therapeutics (FATE)



FATE - Rating as of 30-Sep-13 = NR

Date Rating Change Share Price
1 25-Oct-13 NR to OP \$6.93

Last Daily Data Point: March 12, 2014

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Rating		BMOCM US	BMOCM US	BMOCM US	BMOCM	BMOCM	Starmine
Category	BMO Rating	Universe*	IB Clients**	IB Clients***	Universe****	IB Clients****	Universe
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Hold	Market Perform	56.1%	13.8%	49.0%	54.0%	46.5%	41.8%
Sell	Underperform	5.8%	5.6%	2.0%	7.2%	3.1%	5.7%

- \* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.
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