

Equity Research

March 12, 2014

**Price: \$8.99** (03/11/2014)

**Price Target: NA**

**OUTPERFORM (1)**

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**Key Data**

Symbol **NASDAQ: FATE**

Market Cap (MM) **\$183.0**

Company Quick Take

## *FATE back in the clinic with PUMA Phase II start; interim data 2H14*

**The Cowen Insight**

Fate announced enrollment of the first patient in the Phase II PUMA trial of ProHema, its HSC therapeutic produced by *ex vivo* modulation of umbilical cord blood, using the new nutrient-rich media formulation, in patients with hematologic malignancies, which will be conducted in 10 US sites. Interim data are anticipated in 2H14, with full data on the primary efficacy endpoint expected in mid-2015.

**Trial design:** PUMA (PROHEMA in Umbilical cord blood transplant in Adults) is an open-label, randomized, controlled, multicenter (10 US sites), Phase II trial evaluating ProHema in adult patients with hematologic malignancies who are being treated with double UCBT (umbilical cord blood transplant) after myeloablative (MAB) conditioning or reduced intensity conditioning (RIC). Patients will be randomized 2:1 to receive ProHema plus an unmanipulated CBU or two unmanipulated CBUs. The trial is expected to enroll 60 patients, with 40 assigned to the ProHema arm and 20 to the control arm. Patients will be stratified according to the type of conditioning regimen used (MAB or RIC). Compared with previous trials, the Phase II PUMA trial will incorporate the nutrient-rich media (NRM) formulation, which incorporates a stabilizing agent that prevents cells from lysing, improving product viability and potency and thereby enhancing its therapeutic profile.

**Interim look into PUMA in 2H14:** The data monitoring committee (DMC) will conduct two safety reviews in the study, after the first 6 and 12 patients have been treated with ProHema. Interim data will be released after the 12-patient review has been completed and are anticipated in 2H14, with full data on the primary efficacy endpoint expected in mid-2015. The second interim look will be completed when roughly 1/3 of the trial has been completed (12 ProHema patients and 5-7 patients on the control arm).

**Study Endpoints:** The primary endpoint of the trial is the cumulative incidence of neutrophil engraftment by a pre-specified control median, which will be adjusted based on the median time to neutrophil engraftment for patients in the control arm. Secondary endpoints include time to neutrophil engraftment, cumulative incidence of neutrophil engraftment by Day 42, time to platelet engraftment, cumulative incidence of platelet engraftment by Day 180, graft failure rate, acute GVHD rate, event-free survival, and OS.

**What's next for FATE?** 1) Initiation of Phase Ib trial of ProHema in pediatric patients, mid-2014; 2) Initiation of Phase I trial of ProHema in lysosomal storage disorders, 2H14; 3) Interim data from Phase II PUMA trial, 2H14; 4) IND submission for Wnt7a, YE14; 5) Full data from Phase II PUMA trial, mid-2015; and 6) Initiation of Wnt7a Phase I program, 2015.

**Our thesis on FATE:** Our view on FATE is based on the company's core technology and expertise in the pharmacologic modulation of adult stem cells for the

**Please see addendum of this report for important disclosures.**

development of therapeutics for the treatment of orphan diseases. If successful in its Phase II and Phase III development, we estimate that ProHema can gain significant share in the umbilical cord blood-derived HSCT market, along with share in the bone marrow- and peripheral blood-derived markets as well. Using conservative market penetration assumptions for ProHema (16% of the overall allogeneic HSCT market), we project that it can be a \$360M US/EU product in 2025, with peak US/EU sales of ~\$515M in 2030. These revenue numbers do not account for the upside that exists should ProHema and follow-on products manage to demonstrate utility in rare genetic disorders for which transplantation is not currently used as the standard of care, but is being used investigational and starting to emerge as a potential treatment option. We believe that the combination of the ProHema opportunity with the potential upside from the Wnt7a analog program make FATE an attractive early-stage biotech play. We reiterate our Outperform rating on FATE.

## *Valuation Methodology And Risks*

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### **Valuation Methodology**

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#### **Biotechnology:**

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

### **Investment Risks**

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#### **Biotechnology:**

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

### **Risks To The Price Target**

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Risks to our Outperform rating on FATE shares include: 1) delays and/or clinical setbacks in the development of ProHema, 2) delays and/or setbacks in the development of the Wnt7a analog program, and 3) a change in the appetite for early-stage company risk among healthcare investors.

# Addendum

## Stocks Mentioned in Important Disclosures

Ticker	Company Name
FATE	Fate Therapeutics, Inc.

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**Outperform (1):** The stock is expected to achieve a total positive return of at least 15% over the next 12 months

**Market Perform (2):** The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

**Underperform (3):** Stock is expected to achieve a total negative return of at least 10% over the next 12 months

**Assumption:** The expected total return calculation includes anticipated dividend yield

#### Cowen and Company Rating System until May 25, 2013

**Outperform (1):** Stock expected to outperform the S&P 500

**Neutral (2):** Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

**Assumptions:** Time horizon is 12 months; S&P 500 is flat over forecast period

#### Cowen Securities, formerly known as Dahlgren Rose & Company, Rating System until May 25, 2013

**Buy** – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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**Hold** – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

## Cowen And Company Rating Definitions

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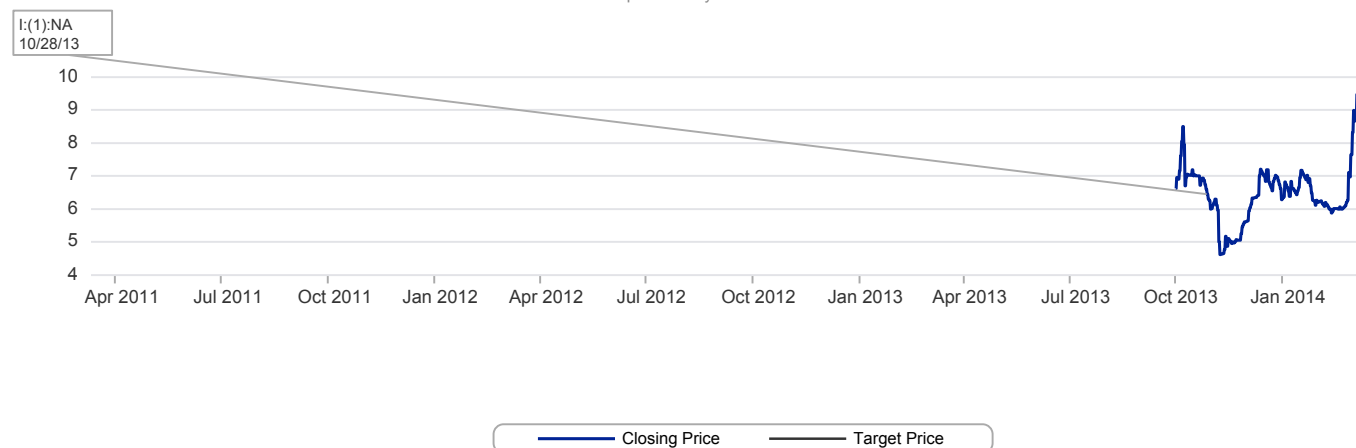
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	415	59.20%	68	16.39%
Hold (b)	270	38.52%	4	1.48%
Sell (c)	16	2.28%	1	6.25%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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### Fate Therapeutics, Inc. Rating History as of 03/11/2014

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#### Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available

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