

Reason for report:

FLASH NOTE

SAGE THERAPEUTICS, INC.

SAGE-547 On Track to Advance into Global Phase III by Mid-2015

• **Bottom Line:** This morning SAGE announced that it has successfully agreed upon a phase III protocol for its pivotal SAGE-547 trial with the FDA in Super Refractory Status Epilepticus (SRSE). We believe the trial design is robust, and relatively in line with investor expectations as SAGE has said that a pivotal study could either be placebo-controlled or open-label and that it sees pros and cons with each. We currently model a SAGE-547 launch in late 2017. **Reiterate OP on SAGE.**

• **SAGE has agreed upon a robust phase III trial design with the FDA, and is on track to initiate its pivotal SAGE-547 study by mid-2015.**

The trial will be placebo-controlled and will enroll 126 patients at up to 150 sites worldwide. Most importantly in our view, the efficacy endpoints, as well as the way patients will be treated in the phase III, are similar to and the same as (respectively) how patients were evaluated and treated in the phase I/II and the emergency IND programs, where SAGE-547 demonstrated ~71% and ~78% success rates on the resolution of status epilepticus. The company will also continue to run a compassionate use program of '547 in SRSE, which we believe could generate additional data that is supportive of an NDA filing.

• **The phase III is powered at 90% to show a stat. sig. difference between the SRSE resolution rates on drug and placebo,** and conservatively assumes about a 35% placebo rate and a less robust drug effect than what has been seen thus far for '547 in the phase I/II and emergency use programs. In addition SAGE will look at various secondary endpoints in the phase III, including measures that explore the rate of recovery, regaining of consciousness, mental status and functional outcome. Patients who fail to respond to initial blinded treatment (SAGE-547 or placebo) may be eligible to be treated with an open-label, higher dose regimen of SAGE-547.

• **SAGE plans to announce additional SAGE-547 data at the Antiepileptic Drug and Device Trials Conference** which is being held in Miami from May 13-15. The company will also report the phase I/II data at the American Association of Neurology (AAN, 4/18-25) which may or may not provide incrementally more data than the last update (late breaking abstracts are not yet out). The phase I/II clinical trial is continuing to enroll patients in an expansion cohort under a protocol amendment, allowing treatment of pediatric patients as young as two years old and investigating a higher dose regimen of SAGE-547. SAGE has continued the phase I/II to keep sites recruiting patients and ready to enroll for the phase III.

Key Stats:

(NASDAQ:SAGE)

S&P 600 Health Care Index:	1,637.91
Price:	\$50.86
52 Week High:	\$55.01
52 Week Low:	\$24.25
Shares Outstanding (mil):	27.6
Market Capitalization (mil):	\$1,403.7

Disclosures Appendix

Analyst Certification

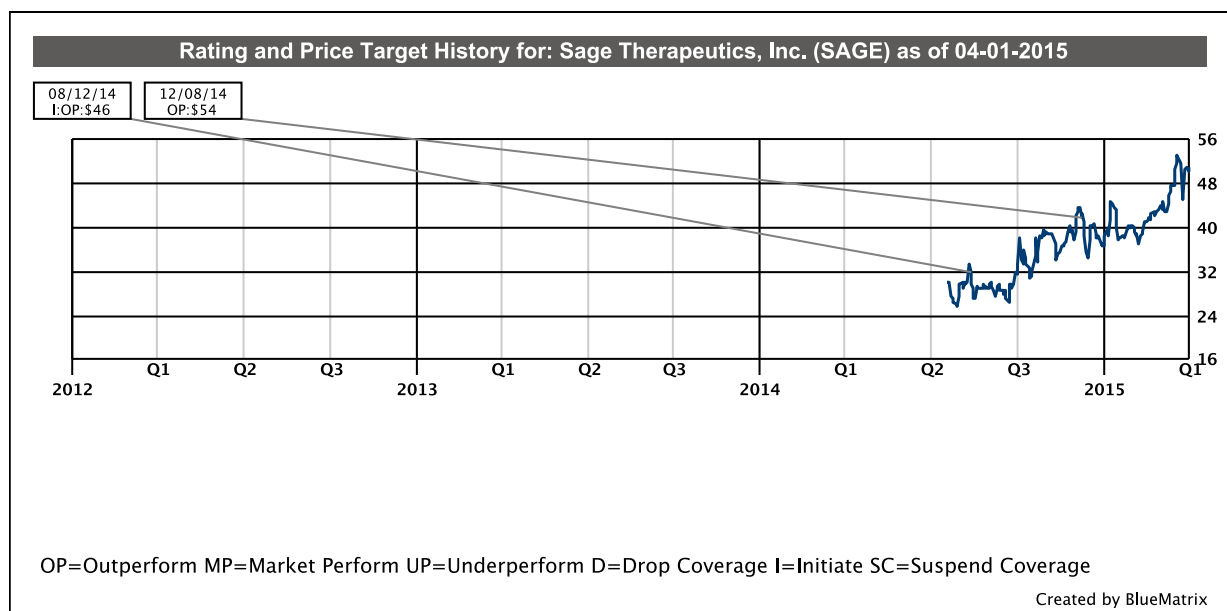
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

We derive a \$54 price target for SAGE shares based on a 12% discount rate and a 3% terminal growth rate. Our base case assumption assumes ~\$1.35B in peak risk-adjusted 2023E sales based on a 75% probability of approval for SAGE-547, and assumes ~\$270MM in peak revenues in 2027E for SAGE-689 and SAGE-217 and ~\$140MM in peak revenues (2027E) for essential tremor.

Risks to Valuation

Risks to our valuation include disappointing clinical data, regulatory setbacks, and commercial shortfalls. Because SAGE has only one product currently being examined in patients, the occurrence of any of these could impact the stock significantly.



Distribution of Ratings/Investment Banking Services (IB) as of 12/31/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	150	70.00	60	40.00
HOLD [MP]	64	30.00	1	2.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

Important Disclosures

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

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In the past 12 months, the Firm has received compensation for providing investment banking services to Sage Therapeutics, Inc. .

Leerink Partners LLC makes a market in Sage Therapeutics, Inc.

Leerink Partners LLC has acted as the manager for a public offering of Sage Therapeutics, Inc. in the past 12 months.

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