

Reason for report:

FLASH NOTE

## SAGE THERAPEUTICS, INC.

### Maturing SAGE-547 Data Provides Continued Support of Robust Effect in SRSE

• **Bottom Line:** This morning SAGE announced additional SAGE-547 data in Super Refractory Epilepticus (SRSE) that continues to support a robust drug effect in patients who do not respond to anti-epilepticus, benzodiazapines and IV anesthesia. In addition to the continued >70% response rate, SAGE also reported that in 12 patients who were followed out to 30 days, those who showed resolved SRSE on their EEG had improved medical outcomes. We believe these data further de-risk the drugs clinical/commercial profile ahead of the initiation of a pivotal phase III study by mid-2015. **Reiterate OP on SAGE.**

• **This morning SAGE announced that in 17 and 9 evaluable patients in the phase I/II and emergency IND program, ~71% and 78% achieved sustained resolution of Status Epilepticus** after receiving '547 therapy. This compares favorably to the ~33% SRSE resolution rate outlined in the literature as well as the 73%/71% response rates reported in November. At baseline, all patients were also measured by the Clinical Global Impression of Severity (CGI-S) scale, which tracks patient progress and treatment response over time; of 12 patients who were evaluated out to day 30, all who responded to SAGE-547 had improved to "mildly ill", while those who did not improve on their EEG remained "severely ill". This is the first time that longer-term durability data has been announced for '547, and the results provide validation of the clinical meaningfulness of EEG as a surrogate endpoint predictive of improved outcomes. 5 deaths were observed in the study; however all were attributed to the patients' underlying condition which included ailments such as metastatic brain tumor, stroke and serious infection.

• **SAGE expects to initiate its phase III study by mid-2015 and plans to provide an update on trial structure in 1Q15.** The company is involved in discussions with the Agency and expects regulatory clarity soon. We believe that an open-label pivotal trial as well as a placebo-controlled study are both possible, and see positives and negatives to each strategy. While an open-label trial could pose incrementally less clinical/regulatory risk and may produce pivotal data more rapidly by requiring a smaller N, a placebo-controlled trial could ultimately augment SAGE's pricing power with hospital formularies/payors. We believe the company is weighing the pros/cons with each strategy, and currently model a 75% probability-of-success based on the encouraging data generated to date.

#### Key Stats:

(NASDAQ:SAGE)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,451.11</b>
<b>Price:</b>	<b>\$44.73</b>
52 Week High:	\$44.98
52 Week Low:	\$24.25
Shares Outstanding (mil):	27.6
Market Capitalization (mil):	\$1,234.5

## Disclosures Appendix

### Analyst Certification

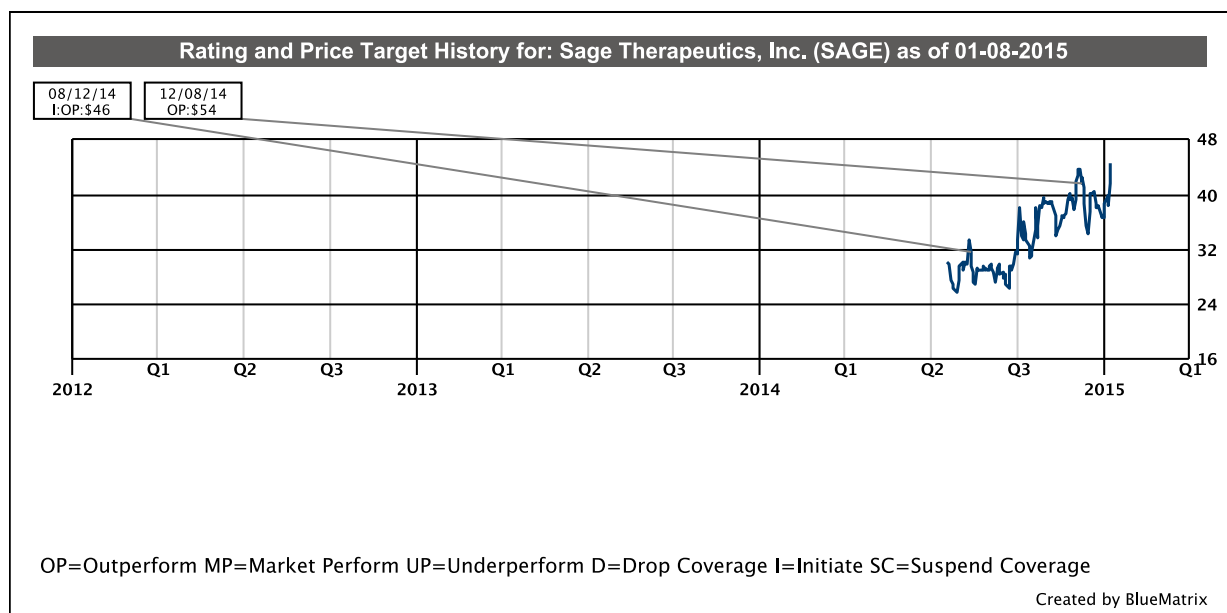
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### 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 ~\$1.35 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 09/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.30	51	37.00
HOLD [MP]	61	30.70	2	3.30
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.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction. MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

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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**Leerink Partners LLC Equity Research**


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