

Reason for report:

FLASH NOTE

SAGE THERAPEUTICS, INC.

SAGE-547 Phase I/II Data Show Robust Response and Set the Stage for Phase III

• **Bottom Line:** This morning, SAGE reported positive data from its Phase I/II SAGE-547 study in Super Refractory Status Epilepticus (SRSE). Top-line data reported from 12 patients, eight males and four females with a mean age of 54 enrolled in the study, show that all 12 patients met the primary endpoint, safety and tolerability. 8/11 evaluable patients were successfully weaned off IV anesthesia and subsequently '547 without the recurrence of status, rendering them treatment successes. SAGE also provided an update on its emergency IND program, which has showed a 5/7 response rate, and the robust data reported this morning lay the framework for discussions with the FDA regarding a pivotal trial, which SAGE hopes to initiate in 1H15. **Reiterate OP on SAGE.**

• **SAGE-547's 73% success rate in Phase I/II is well above the ~30% success rate achieved by the SRSE standard-of-care.** In the study, the mean duration of status epilepticus prior to treatment with SAGE-547 was 11 days, so individuals treated with '547 already failed benzodiazepenes, anti-epileptics, and anesthesia. Thus, at >2x the success rate of the standard-of-care in a highly refractory patient population, we believe the data announced this morning could be sufficient for SAGE to attain breakthrough therapy status. Patients were administered SAGE-547 intravenously for five days while weaning from anesthesia was attempted, and were monitored for four weeks following treatment, which was found to be safe, and has thus paved the way for SAGE to study higher doses in newly recruited patients.

• **Recall that in its last update SAGE noted that 4/4 patients in the Phase I/II were treatment successes and that 5/6 patients in its emergency IND program showed resolution of SRSE,** so the results this morning imply a modestly lower response rate (4/8 or 50%) in the new set of 8 patients. Most important to us, however, the success rate in 13/18 patients appears to separate clearly from the standard-of-care, which would have been expected to resolve status in 6/18 individuals, and therefore de-risks a Phase III in our view for which we currently assume a 75% probability of success.

• **The FDA recently approved a protocol amendment for the Phase 1/2 that will enable SAGE to treat pediatric patients as young as two years old and to increase the dose of SAGE-547** being administered to patients. SAGE is continuing to enroll patients as an expansion cohort in this study, which thus could produce additional de-risking data before pivotal trial results are released.

Key Stats:

(NASDAQ:SAGE)

S&P 600 Health Care Index:	1,348.10
Price:	\$38.72
52 Week High:	\$41.01
52 Week Low:	\$24.25
Shares Outstanding (mil):	27.6
Market Capitalization (mil):	\$1,068.7

Disclosures Appendix

Analyst Certification

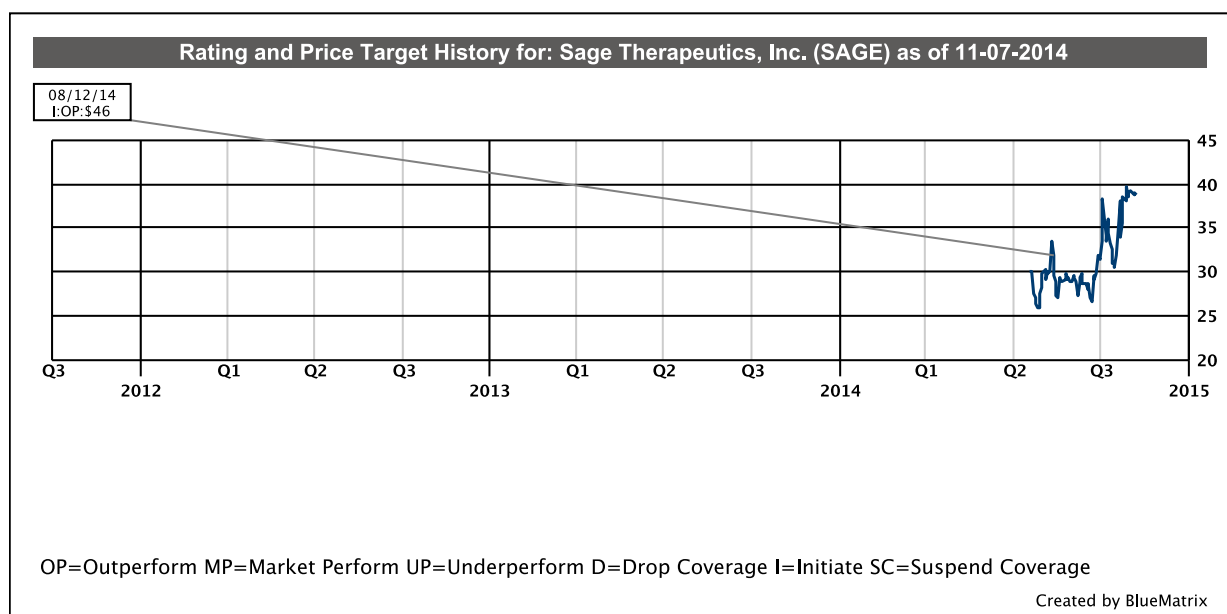
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

We derive a \$46 price target for SAGE shares based on a 12% discount rate and a 3% terminal growth rate. Our base case assumption assumes ~\$1B 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.

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

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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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