# SAGE Therapeutics, Inc. (SAGE)



# SAGE Transfer Coverage, Maintain Buy and \$109 PT

#### What's Incremental

We are transferring coverage of Sage Therapeutics to Edward Nash with a Buy rating and a 12-month price target of \$109. We continue to view Sage as a premier Orphan play that targets significant unmet medical needs in the central nervous system (CNS) space. We recently increased our PT based on the promising data from a Phase II clinical trial in post-partum depression patients. We believe multiple near-term catalysts, combined with a strong pipeline for Orphan CNS disorders, represents an attractive investment opportunity.

- All estimates and projections remain unchanged. Our valuation is primarily based on SAGE-547, a proprietary formulation of the naturallyoccuring hormone allopregnanolone which is a modulator of the neural gamma-amino butyric acid (GABA) receptor. SAGE-547 is being developed for the treatment of the CNS Orphan indication super refractory status epilepticus (SRSE). Sage plans to initiate a pivotal Phase III clinical trial in mid-2015 and we assign a probability of success of 58% in the U.S., 25% in the EU, and 25% in ROW. We model peak WW sales of \$1.7B in 2026 from this program alone.
- The SAGE-547 Phase III STATUS trial remains on track. The randomized, double-blind, placebo-controlled study will enroll approximately 126 SRSE patients aged two or older. The primary endpoint is successful weaning from general anesthesia as well as SAGE-547/placebo and no SRSE recurrence within 24 hours post wean. The FDA has agreed that this primary endpoint is clinically meaningful given the severity of the targeted indication.
- Catalysts remain abundant for 2H15. Sage is conducting a Phase IIa clinical trial of SAGE-547 for the treatment of essential tremor (ET), a common movement disorder similar to seizures. SAGE-547 addresses a broader range of GABA molecules as compared to the current standard of care benzodiazepines, and therefore could potentially provide ET patients with improved efficacy. Top-line data from this double-blind, placebocontrolled, proof-of-concept crossover study are expected to readout in mid-2015. We believe management will base the strategic go/no go decision on the robustness of the signal, and we have not included this indication in our Company valuation.
- Second generation molecules will enter the clinic by year-end 2015. Sage plans to evaluate SAGE-689 and SAGE-217 as adjunct therapy for SRSE or for Orphan epilepsies (such as Dravet and Rett syndromes),

**Edward Nash** 212-319-5578 edward.nash@suntrust.com

Mike Guo. Ph.D. 212-303-4162

mike.guo@suntrust.com

Yun Zhong, Ph.D. 212-303-4193

yun.zhong@suntrust.com

# Buy

Price Target: \$109.00 Prior: \$109.00

| Price (Jul. 10, 2015)           | \$72.87         |
|---------------------------------|-----------------|
| 52-Wk Range                     | \$86.71-\$25.86 |
| Market Cap (\$M)                | \$1,880         |
| ADTV                            | 422,336         |
| Shares Out (M)                  | 25.8            |
| Short Interest Ratio/% Of Float | 11.5%           |
| TR to Target                    | 49.6%           |

| Cash Per Share             | \$7.21  |
|----------------------------|---------|
| Total Debt                 | \$0.0   |
| Cash And Equivalents (\$M) | \$222.9 |

|                        | 2014E     | 201    | 5E     | 2016   | E      |  |  |  |  |
|------------------------|-----------|--------|--------|--------|--------|--|--|--|--|
|                        |           | Curr.  | Prior  | Curr.  | Prior  |  |  |  |  |
| Reven                  | ue (\$M)  |        |        |        |        |  |  |  |  |
| FY                     | 0         | 0      | 0      | 0      | 0      |  |  |  |  |
| EPS A                  | djusted   |        |        |        |        |  |  |  |  |
| FY                     | ( 1.67)A  | (2.83) | (2.83) | (3.15) | (3.15) |  |  |  |  |
| P/E                    | NM        | NM     |        | NM     |        |  |  |  |  |
| Conse                  | ensus Rev |        |        |        |        |  |  |  |  |
| FY                     | 0         | 0      | 0      | 0      | 0      |  |  |  |  |
| Consensus EPS Adjusted |           |        |        |        |        |  |  |  |  |
| FY                     | ( 2.51)A  | (2.09) | (2.09) | (2.44) | (2.44) |  |  |  |  |
| FYE                    | Dec       |        |        |        |        |  |  |  |  |



respectively. A novel program (likely targeting the NMDA receptor) is also expected to be announced by year-end 2015.



Figure 1: SAGE-547 for Super Refractory Status Epilepticus (SRSE)



## SAGE-547 for Super Refractory Status Epilepticus (SRSE)



- Drug: SAGE-547
- Type: a proprietary formulation of allopregnanolone, a naturally-ocurring neural molecule, and a GABA receptor modulator
- · Indication: Super Refractory Status Epilepticus (SRSE), a CNS Orphan indication
- . Market Size: 22K, 35K, and 35K patients in the U.S., EU, and ROW, respectively
- Revenue Potential: \$1B, \$0.59B, and \$0.1B in 2026 in the U.S., EU, and ROW, respectively
- Current Stage: Top-line data from a Phase I/II clinical trial reported in November 2014 and feedback from the End-of-Phase II meeting reported in April 2015
- Recent Data: Updated positive data from the Phase I/II study announced in May 2015 and presented at the Antiepileptic Drug and Device Trials XIII Conference
- Next Stage: Initiation of a pivotal Phase III clinical trial in mid-2015
- Primary Endpoint: Successful weaning from general anesthesia as well as SAGE-547/placebo and no SRSE recurrence within 24 hours post wean

Source: STRH analysis and Company reports

Figure 2: SAGE-547 for Postpartum Depression (PPD)

# SAGE-547 for Postpartum Depression (PPD)



- Drug: SAGE-547
- Type: a proprietary formulation of allopregnanolone, a naturally-ocurring neural molecule, and a GABA receptor modulator
- Indication: Postpartum Depression (PPD)
- Market Size: ~15-20% of the ~4M postpartum U.S. women (could be conservative, excludes stillborn and miscarriages) could be addressed by SAGE's approach
- Revenue Potential: We have not included in our revenue buildup model but we assign a \$25 value for SAGE's R&D platform, including SAGE-547/novel compounds addressing PPD
- Current Stage: A single-center, exploratory open-label Phase II clinical trial is ongoing
- Recent Data: Top-line data from the first four patients in the Phase II study announced in June 2015
- Primary Endpoint: Hamilton Rating Scale for Depression (HAM-D, rates severity of 17 depression symptoms such as insomnia, agitation, anxiety, weight loss and low mood)
- Next Stage: Completion of the exploratory Phase II clinical trial

Source: STRH analysis and Company reports



Figure 3: Sage Therapeutics Upcoming Milestones

| Product        | Timing      | Indication                               | Event                               |
|----------------|-------------|--|-------------------------------------|
| SAGE-547       | By mid-2015 | Essential Tremor                         | Phase II topline data               |
| SAGE-547       | By Mid-2015 | Super refractory status epilepticus (IV) | Initiate the Phase III STATUS trial |
| SAGE-689       | Late-2015   | Adjunctive Status Epilepticus (IV)       | Initiate Phase I testing            |
| SAGE-217       | Late-2015   | Orphan Genetic Seizure Disorders (oral)  | Initiate Phase I testing            |
| NMDA modulator | Late-2015   | Undisclosed orphan indication            | Announce next program               |

Source: STRH analysis and Company reports



## Sage Therapeutics Revenue Buildup Model

| •   | •       |         |          |          |          |           |          |          |         |                |                        |                        |                        |                        |                              |                        |                        |                   |
|---|---------|---------|----------|----------|----------|-----------|----------|----------|---------|----------------|------------------------|------------------------|------------------------|------------------------|------------------------------|------------------------|------------------------|-------------------|
| SAGE-547 for super refractory status epilepticus                        |         |         |          |          |          |           |          |          |         |                |                        |                        |                        |                        |                              |                        |                        |                   |
| U.S.  | FY      | FY      | Mar      | Jun      | Sep      | Dec       | FY       | FY       | FY      | FY             | FY                     | FY                     | FY                     | FY                     | FY                           | FY                     | FY                     | FY                |
| •   | 2013A   | 2014E   | Q1 2015A | Q2 2015E | Q3 2015E | Q4 2015E  | 2015E    | 2016E    | 2017E   | 2018E          | 2019E                  | 2020E                  | 2021E                  | 2022E                  | 2023E                        | 2024E                  | 2025E                  | 2026E             |
| U.S. Population   | 316,149 | 319,928 | 320,544  | 321,161  | 321,779  | 322,398   | 321,470  | 323,946  | 326,440 | 328,954        | 331,487                | 334,039                | 336,611                | 339,203                | 341,815                      | 344,447                | 347,099                | 349,772           |
| 'Incidence of status epilepticus  | 0.044%  | 0.044%  | 0.044%   | 0.044%   | 0.044%   | 0.044%    | 0.044%   | 0.044%   | 0.044%  | 0.044%         | 0.044%                 | 0.044%                 | 0.044%                 | 0.044%                 | 0.044%                       | 0.044%                 | 0.044%                 | 0.044%            |
| No. U.S. Status epilepticus patients diagnosed per year                 | 140     | 141     | 142      | 142      | 142      | 143       | 142      | 143      | 144     | 145            | 147                    | 148                    | 149                    | 150                    | 151                          | 152                    | 153                    | 155               |
| Incidence hospitalizations due to AE                                    | 0.013%  | 0.013%  | 0.013%   | 0.013%   | 0.013%   | 0.013%    | 0.013%   | 0.013%   | 0.013%  | 0.013%         | 0.013%                 | 0.013%                 | 0.013%                 | 0.013%                 | 0.013%                       | 0.013%                 | 0.013%                 | 0.013%            |
| No. of hospitalized SE patients (2nd line SE)                           | 40      | 40      | 40       | 40       | 40       | 40        | 40       | 40       | 41      | 41             | 41                     | 42                     | 42                     | 42                     | 43                           | 43                     | 43                     | 44                |
| % of all SE patients who become refractory to 1st and 1nd line therapy  | 23%     | 23%     | 23%      | 23%      | 23%      | 23%       | 23%      | 23%      | 23%     | 23%            | 23%                    | 23%                    | 23%                    | 23%                    | 23%                          | 23%                    | 23%                    | 23%               |
| No. Refractory status epilepticus (RSE) patients                        | 32      | 32      | 32       | 32       | 32       | 32        | 32       | 32       | 33      | 33             | 33                     | 33                     | 34                     | 34                     | 34                           | 34                     | 35                     | 35                |
| % of SE patients that become super refractory                           | 16%     | 16%     | 16%      | 16%      | 16%      | 16%       | 16%      | 16%      | 16%     | 16%            | 16%                    | 16%                    | 16%                    | 16%                    | 16%                          | 16%                    | 16%                    | 16%               |
| No. Super refractory status epilepticus (SRSE) patients                 | 22      | 22      | 22       | 22       | 22       | 22        | 22       | 22       | 23      | 23             | 23                     | 23                     | 23                     | 23                     | 24                           | 24                     | 24                     | 24                |
| % penetration of SAGE-547   | 0%      | 0%      | 0%       | 0%       | 0%       | 0%        | 0%       | 0%       | 0%      | 7%             | 28%                    | 40%                    | 55%                    | 60%                    | 65%                          | 68%                    | 70%                    | 72%               |
| No. of SRSE patients treated with SAGE-547                              | 0       | 0       | 0        | 0        | 0        | 0         | 0        | 0        | 0       | 2              | 6                      | 9                      | 13                     | 14                     | 15                           | 16                     | 17                     | 17                |
| Gross annual WAC per patient  | \$ -    | s -     | s - !    | s -      | s - :    | \$ -      | \$ -     | s - s    | - 5     | 50,000         | \$ 52,000              | \$ 54,080              | \$ 56,243              | \$ 58,493              | \$ 60,833 \$                 | 63,266 \$              | 65,797 \$              | 68,428            |
| Net annual WAC per patient  | s -     | s -     | s - :    | s -      | S - :    | s -       | s - I    | s - s    |         | 40,000         | \$ 41,600              | \$ 43.264              | \$ 44,995              | \$ 46,794              | \$ 48,666 \$                 | 50.613 \$              | 52,637 \$              | 54,743            |
| Total U.S. SAGE-547 sales (\$000s)                                      | s -     | s -     | s - :    | s -      | s -      | s -       | s -      | \$0      | \$0     | \$63,810       | \$267,493              | \$400,479              | \$577,094              | \$659,781              | \$749,077                    | \$821,271              | \$886,014              | \$955,079         |
| ,                                 |         |         |          |          |          |           |          |          |         |                |                        |                        |                        |                        |                              |                        |                        |                   |
| E.U.  | FY      | FY      | Mar      | Jun      | Sep      | Dec       | FY       | FY       | FY      | FY             | FY                     | FY                     | FY                     | FY                     | FY                           | FY                     | FY                     | FY                |
| _   | 2013A   | 2014E   | Q1 2015A | Q2 2015E | Q3 2015E | Q4 2015E  | 2015E    | 2016E    | 2017E   | 2018E          | 2019E                  | 2020E                  | 2021E                  | 2022E                  | 2023E                        | 2024E                  | 2025E                  | 2026E             |
| E.U. Population   | 501,412 | 502,102 |          | 502,378  | 503,069  | 502,654   | 502,723  | 503,829  | 504,938 | 506,049        | 507,162                | 508,278                | 509,396                | 510,517                | 511,640                      | 512,765                | 513,893                | 515,024           |
| Incidence of status epilepticus   | 0.044%  | 0.044%  | 0.044%   | 0.044%   | 0.044%   | 0.044%    | 0.044%   | 0.044%   | 0.044%  | 0.044%         | 0.044%                 | 0.044%                 | 0.044%                 | 0.044%                 | 0.044%                       | 0.044%                 | 0.044%                 | 0.044%            |
| No. E.U. Status epilepticus patients diagnosed per year                 | 221     | 221     | 221      | 221      | 221      | 221       | 221      | 222      | 222     | 223            | 223                    | 224                    | 224                    | 225                    | 225                          | 226                    | 226                    | 227               |
| Incidence hospitalizations due to AE                                    | 0.013%  | 0.013%  | 0.013%   | 0.013%   | 0.013%   | 0.013%    | 0.013%   | 0.013%   | 0.013%  | 0.013%         | 0.013%                 | 0.013%                 | 0.013%                 | 0.013%                 | 0.013%                       | 0.013%                 | 0.013%                 | 0.013%            |
| No. of hospitalized SE patients (2nd line SE)                           | 65      | 65      | 65       | 65       | 65       | 65        | 65       | 65       | 66      | 66             | 66                     | 66                     | 66                     | 66                     | 67                           | 67                     | 67                     | 67                |
| % of all SE patients who become refractory to 1st and 1nd line therapy  | 23%     | 23%     | 23%      | 23%      | 23%      | 23%       | 23%      | 23%      | 23%     | 23%            | 23%                    | 23%                    | 23%                    | 23%                    | 23%                          | 23%                    | 23%                    | 23%               |
| No. Refractory status epilepticus (RSE) patients                        | 50      | 50      | 50       | 50       | 50       | 50        | 50       | 50       | 50      | 50             | 50                     | 51                     | 51                     | 51                     | 51                           | 51                     | 51                     | 51                |
| % of SE patients that become super refractory                           | 16%     | 16%     | 16%      | 16%      | 16%      | 16%       | 16%      | 16%      | 16%     | 16%            | 16%                    | 16%                    | 16%                    | 16%                    | 16%                          | 16%                    | 16%                    | 16%               |
| No. Super refractory status epilepticus (SRSE) patients                 | 35      | 35      | 35       | 35       | 35       | 35        | 35<br>0% | 35<br>0% | 35      | 35             | 35                     | 35                     | 35                     | 15%                    | 35                           | 35                     | 35                     | 36                |
| % penetration of SAGE-547   | 0%      | 0%      | 0%       | 0%       | 0%       | 0%        | 0%       | 0%       | 0%      | 0%             | 4%                     | 8%                     | 12%                    | 15%                    | 20%                          | 32%                    | 38%                    | 40%               |
| No. of SRSE patients treated with SAGE-547                              | 1. "    | 0       | 0        | , oi     | . "      | . "       | . "      | ء ا      | . "     | . "            |                        | 3                      |                        |                        |                              |                        | 13                     | 14                |
| Gross annual WAC per patient  Net annual WAC per patient                | \$ -    | \$ -    | \$ -     | - 1      | \$ -     | -         | \$ -     | 5 - 3    | -       | -              | \$ 52,000<br>\$ 41,600 | \$ 52,000<br>\$ 41,600 | \$ 52,000<br>\$ 41,600 | \$ 52,000<br>\$ 41,600 | \$ 52,000 \$<br>\$ 41,600 \$ | 52,000 \$<br>41,600 \$ | 52,000 \$<br>41,600 \$ | 52,000<br>41,600  |
| Total E.U. SAGE-547 sales (\$000s)                                      | \$ -    | \$ .    | S -      | •        | S -      | • -       | \$ -     | \$0      | \$0     | \$0            | \$58,174               | \$ 41,600<br>\$116,604 | \$175,291              | \$ 41,600              | \$293,438                    | \$470.534              | \$559,989              | \$590,759         |
| 10th 2.01 07/02 047 tailed (\$6000)                                     |         |         |          | ·        | •        | ·         | ·        | Ų į      | 40      | <del>V</del> O | 400,114                | \$110,004              | ψ110,201 j             | <b>Q2</b> 10,000       | <b>\$250,400</b>             | <b>\$470,004</b>       | 4000,000               | <b>\$</b> 000,700 |
| ROW   | FY      | FY      | Mar      | Jun      | Sep      | Dec       | FY       | FY       | FY      | FY             | FY                     | FY                     | FY                     | FY                     | FY                           | FY                     | FY                     | FY                |
|   | 2013A   | 2014E   | Q1 2015A | Q2 2015E | Q3 2015E | Q4 2015E  | 2015E    | 2016E    | 2017E   | 2018E          | 2019E                  | 2020E                  | 2021E                  | 2022E                  | 2023E                        | 2024E                  | 2025E                  | 2026E             |
| ROW reimbursable Population   | 501,412 | 503,924 | 506,446  | 504,932  | 507,459  | 505,942   | 506,195  | 510,244  | 514,326 | 518,441        | 522,588                | 526,769                | 530,983                | 535,231                | 539,513                      | 543,829                | 548,180                | 552,565           |
| Incidence of status epilepticus   | 0.041%  | 0.041%  | 0.041%   | 0.041%   | 0.041%   | 0.041%    | 0.041%   | 0.041%   | 0.041%  | 0.041%         | 0.041%                 | 0.041%                 | 0.041%                 | 0.041%                 | 0.041%                       | 0.041%                 | 0.041%                 | 0.041%            |
| No. E.U. Status epilepticus patients diagnosed per year                 | 206     | 207     | 208      | 207      | 208      | 207       | 208      | 209      | 211     | 213            | 214                    | 216                    | 218                    | 219                    | 221                          | 223                    | 225                    | 227               |
| Incidence hospitalizations due to AE                                    | 33%     | 33%     | 33%      | 33%      | 33%      | 33%       | 33%      | 33%      | 33%     | 33%            | 33%                    | 33%                    | 33%                    | 33%                    | 33%                          | 33%                    | 33%                    | 33%               |
| No. of hospitalized SE patients (2nd line SE)                           | 68      | 68      | 69       | 68       | 69       | 68        | 68       | 69       | 70      | 70             | 71                     | 71                     | 72                     | 72                     | 73                           | 74                     | 74                     | 75                |
| % of all SE patients who become refractory to 1st and 1nd line therapy  | 70%     | 70%     | 70%      | 70%      | 70%      | 70%       | 70%      | 70%      | 70%     | 70%            | 70%                    | 70%                    | 70%                    | 70%                    | 70%                          | 70%                    | 70%                    | 70%               |
| No. Refractory status epilepticus (RSE) patients                        | 47      | 48      | 48       | 48       | 48       | 48<br>71% | 48       | 48       | 49      | 49             | 49                     | 50                     | 50                     | 51                     | 51                           | 52<br>71%              | 52                     | 52                |
| % of SE patients that become super refractory                           | 71%     | 71%     | 71%      | 71%      | 71%      | /1%       | 71%      | 71%      | 71%     | 71%            | 71%                    | 71%                    | 71%                    | 71%                    | 71%                          | /1%                    | 71%                    | 71%               |
| No. Super refractory status epilepticus (SRSE) patients                 | 34      | 34      | 34       | 34       | 34       | 34        | 34       | 35<br>0% | 35      | 35             | 35                     | 36                     | 36<br>4%               | 36<br>5%               | 36<br>6%                     | 37<br>7%               | 37                     | 37                |
| % penetration of SAGE-547   | 0%      | 0%      | 0%       | 0%       | 0%       | 0%        | 0%       | 0%       | 0%      | 0%             | 1%                     | 2%                     | 4%                     | 5%                     | 6%                           | /%                     | 8%                     | 9%                |
| No. of SRSE patients treated with SAGE-547 Gross annual WAC per patient |         | r. "    | 0        | إن       | . ا      | . "       | , "      | ء ان     | , "I.   | . "            | \$ 50.000              | \$ 50,000              | S 50,000               | \$ 50.000              | \$ 50.000 \$                 | 50.000 \$              | 50.000 S               | 50,000            |
| Net annual WAC per patient  | , .     |         | -        | - 1      | •        | -         | 9 -      | . 1      | - 1     |                | \$ 40,000              | \$ 50,000<br>\$ 40,000 | \$ 50,000<br>\$ 40,000 | \$ 50,000<br>\$ 40,000 | \$ 50,000 \$<br>\$ 40,000 \$ | 40,000 \$              | 50,000 \$<br>40,000 \$ | 40,000            |
| Total ROW SAGE-547 sales (\$000s)                                       | \$ -    | •       | \$ .     | •        | •        | -         | •        | S0       | \$0     | \$0            | \$7,071                | \$ 40,000<br>\$28,509  | \$ 40,000              | \$ 40,000<br>\$72,417  | \$87,595                     | \$103.012              | \$118,670              | \$134.572         |
| Total NOTE ONOL-241 Sales (40003)                                       |         |         |          | • • •    | • •      |           | φ -      | ψU       | ψU      | <b>3</b> 0     | φ1,011                 | 420,309                | φυ1,414                | φι 2,411               | 401,333                      | φ103,01Z               | \$110,070              | \$134,37Z         |
| Total WW SAGE-547 sales (\$000s)  | \$ -    | \$ -    | s - :    | \$ -     | s - :    | \$ -      | \$ -     | \$0      | \$0     | \$63,810       | \$332,738              | \$545,591              | \$809,859              | \$951,793              | \$1,130,111                  | \$1,394,818            | \$1,564,672            | \$1,680,410       |
|   |         |         |          |          |          |           |          |          |         |                |                        |                        |                        |                        |                              |                        |                        |                   |

Source: SunTrust Robinson Humphrey



## Sage Therapeutics P&L Model

| (\$thousands, except per share data)  | FY<br>2012A                 |            | FY<br>2013A               |    | FY<br>2014A                          | Mar<br>Q1 2015A                  | Jun<br>Q2 2015E | Sep<br>Q3 2015E | Dec<br>Q4 2015E | 2    | FY<br>2015E               | FY<br>2016E                 | FY<br>2017E                        | FY<br>2018E      | FY<br>2019E      |      | Υ<br>20E                            |
|---|-----------------------------|------------|---------------------------|----|--------------------------------------|----------------------------------|-----------------|-----------------|-----------------|------|---------------------------|-----------------------------|------------------------------------|------------------|------------------|------|-------------------------------------|
| Revenue<br>SAGE-547   | \$ -                        | 7          | \$ -                      | \$ | -                                    | -                                | -               | -               | -               | \$   | -                         | \$ -                        | \$ -                               | \$ 63,810        | \$ 332,738       | \$ 5 | 545,591                             |
| Total Revenue   | \$ -                        |            | \$ -                      | \$ | -                                    | \$ -                             | \$ -            | \$ -            | \$ -            | \$   | -                         | \$ -                        | \$ -                               | \$ 63,810        | \$ 332,738       | \$ 5 | 545,591                             |
| COGS<br>Gross profit  | -                           | 7          | -                         |    | -                                    | -                                | -               | -               | -               | •    | -                         | -                           | -                                  | 5,105<br>58,705  |                  |      | 60,015<br>485,576                   |
| Operating expense<br>R&D (GAAP)<br>SG&A (GAAP)  | 7,22<br>2,40                |            | 14,357<br>3,922           |    | 24,100<br>9,710                      | 12,900<br>3,997                  | 14,412<br>5,002 | 15,003<br>5,157 |                 |      | 58,317<br>20,158          | 70,223<br>30,122            | 80,232<br>50,033                   | 90,152<br>82,823 |                  |      | 110,532<br>100,213                  |
| Total operating expense   | 9,63                        | 31         | 18,279                    | 7  | 33,810                               | 16,897                           | 19,414          | 20,160          | 22,004          |      | 78,475                    | 100,345                     | 130,265                            | 172,975          | 190,474          | 2    | 210,745                             |
| Operating income (loss)   | (9,63                       | 31)        | (18,279)                  |    | (33,810)                             | (16,897)                         | (19,414)        | (20,160         | (22,004         | )    | (78,475)                  | (100,345)                   | (130,265)                          | (114,270)        | 105,663          | 2    | 274,831                             |
| Interest Income (expense), net<br>Other income (expense), net<br>Total Other Income                                       |                             | (1)<br>(1) | 1<br>(3)<br>(2)           |    | 8<br>(9)<br>(1)                      | 21<br>5<br>26                    | 50<br>-<br>50   | 85<br>-<br>85   | -               |      | 252<br>5<br>257           | 65<br>5<br>70               | 85<br>10<br>95                     | 87<br>20<br>107  | 115<br>40<br>155 |      | 230<br>75<br>305                    |
| Income before income taxes Provision for income taxes Net gain (loss) Accretion of redeemable convertible preferred stock | (9,63<br>-<br><b>(9,6</b> 3 |            | (18,281)<br>-<br>(18,281) |    | (33,811)<br>-<br>(33,811)<br>(2,294) | (16,871)<br>-<br><b>(16,871)</b> | -               | -               | -               |      | (78,218)<br>-<br>(78,218) | (100,275)<br>-<br>(100,275) | (130,170)<br>-<br><b>(130,170)</b> | -                | 5,291            |      | 275,136<br>27,514<br><b>247,623</b> |
| Net gain (loss) applicable to common shareholders   | \$ (9,63                    | 36)        | \$ (18,288)               | \$ | (36,105)                             | \$ (16,871)                      | \$ (19,364)     | \$ (20,075      | ) \$ (21,908    | \$   | (78,218)                  | \$ (100,275)                | \$ (130,170)                       | \$ (114,162)     | \$ 100,527       | \$ 2 | 247,623                             |
| GAAP EPS (diluted)  | \$ (2.7                     | 74) 5      | \$ (12.26)                | \$ | (1.67)                               | \$ (0.66)                        | \$ (0.70)       | \$ (0.70        | ) \$ (0.76      | ) \$ | (2.83)                    | \$ (3.15)                   | \$ (3.95)                          | \$ (3.22)        | \$ 2.58          | \$   | 6.04                                |
| Weighted shares outstanding basic and diluted (k)   | 3,522,60                    | )7         | 1,492                     |    | 21,574                               | 25,655                           | 27,805          | 28,551          | 28,694          |      | 27,676                    | 31,838                      | 32,989                             | 35,472           | 39,029           |      | 40,980                              |

Source: SunTrust Robinson Humphrey



### **Company Description**

SAGE Therapeutics, Inc. is a biopharmaceutical company focused on developing and commercializing novel medicines to treat life threatening, rare central nervous system disorders. The Company's lead program, SAGE-547, is in clinical development for super-refractory status epilepticus and is the first of several compounds the Company is developing in its portfolio of potential seizure medicines. Sage's robust chemistry platform has generated multiple new compounds that target the GABA-A and NMDA receptors, which are well-characterized with regard to their role in many psychiatric and neurological disorders.

#### **Investment Thesis**

SAGE is positioning itself as a premier Orphan play, focused on central nervous system (CNS) diseases of high unmet need, with well-defined molecular characteristics and likely short development timelines. SAGE is one of the few players in the CNS space, a field with significant unmet need – that has been historically difficult to attain success in drug development. The Company recently went public, with the key strategy to use its broad platform (chemical modulators of brain molecules) to focus on drug development for CNS indications that are: 1) well-defined from a molecular perspective, and 2) have short drug development timelines (small numbers of patients, short clinical trial duration). SAGE's lead drug candidate is SAGE-547, a modulator of the neural gamma-amino butyric acid (GABA) receptor. SAGE-547 is about to enter pivotal testing in mid-2015 for super-refractory status epilepticus, a rare type of epilepsy characterized by persistent seizures (>24 hours), in spite of treatment with multiple rounds of anesthetics. The Company has two second generation molecules in the pipeline (SAGE-217 and SAGE-689) expected to enter the clinic in late-2015, as well as a platform of early stage modulators (N-Methyl-D-aspartic acid receptor, NMDA) of cellular brain function, slated to expand the epilepsy/CNS Orphan disease franchise.

### Valuation and Risks

We arrive at our price target of \$109 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes \$65.17/share to SAGE-547's U.S. sales, \$10.89 to SAGE-547's E.U. sales, \$0.63 to SAGE-547's ROW sales, \$25.00 to the R&D platform including SAGE-547/other molecules contribution to post-partum depression, and \$7.21/share to cash. We assign SAGE-547 a probability of success of 58% in the U.S., 25% in the E.U., and 25% in ROW. We assume a discount rate of 10% and a 1% terminal growth rate to SAGE-547 in the U.S. and the E.U., and no terminal value for SAGE-547 in ROW.

### Risks:

- Clinical Risk: SAGE-547 may fail to repeat its 71% to 78% response rate from Phase II trials and eIND use in a pivotal trial. It is possible that both the Phase II and eIND patients had a higher chance of recovering from SRSE than the ~30% chance quoted by SAGE, and of the 30% to 50% chance quoted by our physician consultants. This could be due to the inclusion/exclusion criteria used in Phase II, or another reason altogether. Although preclinical rationale for SAGE-547 is suggestive that the compound could have utility in ET and PPD, the benefit in animals may not translate well in humans. Finally, although they have similar putative mechanisms of action, there is some chance that proof-of-concept for SAGE-547 does not read through to other GABA modulators SAGE-689 and SAGE-217.
- Regulatory risk: The FDA may require more rigorous clinical trials than we anticipate. We believe that SAGE's expected Phase III endpoint of being seizure-free after the patient is weaned from both general anesthesia and SAGE-547 should be appropriate. However, the FDA may ask for a randomized controlled study, which may be difficult to set up given the variability in standard of care among different treatment centers. Longer term follow-up could be required, for example an endpoint such as % of patients who are seizure free one month after wean.
- Commercial risk: SAGE plans to target the relatively small number of ICUs (~900 hospitals in the U.S.) and epilepsy treatment centers (~200 in the U.S.), where SRSE patients are treated. E.U. has a comparable number of centers. The remains a commercial risk (albeit low) that SAGE is unable to effectively reach these patients.



- Competitive Risk: Although we are not aware of any significant competitive drugs in development
  for status epilepticus (SE), Marinus Pharmaceuticals (MRNS) is developing ganaxolone, a similar
  GABA-receptor targeted agent (although restricted to hitting the synaptic receptors), for the treatment
  of other forms of epilepsy and Fragile X syndrome. Although ganaxolone is unlikely to be approved
  for SE without clinical trials in that population, if the drug does become available it could be used
  off-label.
- Financial risk: Given the expenses associated with conducting clinical trials and launch of the product, we anticipate that SAGE may have to issue additional equity through follow-on offerings

## **Analyst Certification**

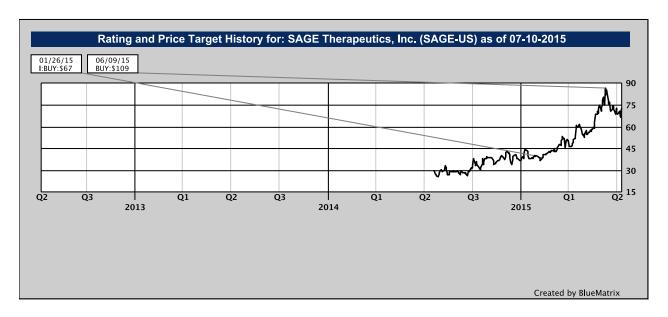
I, Edward Nash, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

## **Required Disclosures**

SunTrust Robinson Humphrey, Inc. makes a market in the following companies at the time of this report: SAGE-US

Analyst compensation is based upon stock price performance, quality of analysis, communication skills, and the overall revenue and profitability of the firm, including investment banking revenue.

As a matter of policy and practice, the firm prohibits the offering of favorable research, a specific research rating or a specific target price as consideration or inducement for the receipt of business or compensation. In addition, associated persons preparing research reports are prohibited from owning securities in the subject companies.





## STRH Ratings System for Equity Securities

3 designations based on total returns\* within a 12-month period\*\*

- Buy total return ≥ 15% (10% for low-Beta securities)\*\*\*
- **Reduce** total return ≤ negative 10% (5% for low Beta securities)
- Neutral total return is within the bounds above
- NR NOT RATED, STRH does not provide equity research coverage
- CS Coverage Suspended
- \*Total return (price appreciation + dividends)
- \*\*Price targets are within a 12-month period, unless otherwise noted
- \*\*\*Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:

D = drop coverage

I = initiate coverage

T = transfer coverage

SunTrust Robinson Humphrey ratings distribution (as of 07/13/2015):

| Coverage Universe | )     |         | Investment Banking Clients Past 12 Months |       |         |  |  |  |  |
|-------------------|-------|---------|---|-------|---------|--|--|--|--|
| Rating            | Count | Percent | Rating                                    | Count | Percent |  |  |  |  |
| Buy               | 308   | 54.13%  | Buy                                       | 118   | 38.31%  |  |  |  |  |
| Neutral           | 255   | 44.82%  | Neutral                                   | 56    | 21.96%  |  |  |  |  |
| Sell/Reduce       | 6     | 1.05%   | Sell/Reduce                               | 1     | 16.67%  |  |  |  |  |

### **Other Disclosures**

Information contained herein has been derived from sources believed to be reliable but is not guaranteed as to accuracy and does not purport to be a complete analysis of the security, company or industry involved. This report is not to be construed as an offer to sell or a solicitation of an offer to buy any security. SunTrust Robinson Humphrey, Inc. and/or its officers or employees may have positions in any securities, options, rights or warrants. The firm and/or associated persons may sell to or buy from customers on a principal basis. Investors may be prohibited in certain states from purchasing some overthe-counter securities mentioned herein. Opinions expressed are subject to change without notice. The information herein is for persons residing in the United States only and is not intended for any person in any other jurisdiction.

SunTrust Robinson Humphrey, Inc.'s research is provided to and intended for use by Institutional Accounts as defined in FINRA Rule 4512(c). The term "Institutional Account" shall mean the account of: (1) a bank, savings and loan association, insurance company or registered investment company; (2) an investment adviser registered either with the SEC under Section 203 of the Investment Advisers Act or with a state securities commission (or any agency or office performing like functions); or (3) any other person (whether a natural person, corporation, partnership, trust or otherwise) with total assets of at least \$50 million.

SunTrust Robinson Humphrey, Inc. is a registered broker-dealer and a member of FINRA and SIPC. It is a service mark of SunTrust Banks, Inc. SunTrust Robinson Humphrey, Inc. is owned by SunTrust Banks, Inc. ("SunTrust") and affiliated with SunTrust Investment Services, Inc. Despite this affiliation, securities recommended, offered, sold by, or held at SunTrust Robinson Humphrey, Inc. and at SunTrust Investment Services, Inc. (i) are not insured by the Federal Deposit Insurance Corporation; (ii) are not deposits or other obligations of any insured depository institution (including SunTrust Bank); and (iii) are subject to investment risks, including the possible loss of the principal amount invested. SunTrust Bank may have a lending relationship with companies mentioned herein.

© SunTrust Robinson Humphrey, Inc. 2015 . All rights reserved. Reproduction or quotation in whole or part without permission is forbidden.

**ADDITIONAL INFORMATION IS AVAILABLE** at our website, **www.suntrustrh.com**, or by writing to: SunTrust Robinson Humphrey, Research Department, 3333 Peachtree Road N.E., Atlanta, GA 30326-1070