## **US Equity Research**

2 April 2015

#### **BUY**

unchanged

**PRICE TARGET** US\$58.00 unchanged

Price (2-Apr) Ticker

US\$48.17 SAGE-NASDAQ

156.7

1.039

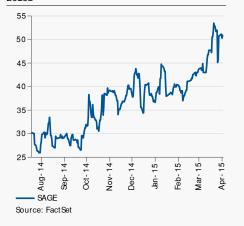
21.6

52-Week Range (US\$): 24.25 - 55.01 Avg Daily Vol (M): Shares Out. (M) : Market Cap (US\$M):

FYE Dec	2014A	2015E	2016E
Sales (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(1.67)	(1.04)	(1.06)

Quarterly Sales	Q1	Q2	Q3	Q4
2014A	0.0	0.0	0.0	0.0
2015E	0.0	0.0	0.0	0.0
20165				

Quarterly EPS Adj&Dil	Q1	Q2	QЗ	Q4
2014A	(3.70)	(4.57)	(0.50)	(0.26)
2015E	(0.23)	(0.24)	(0.27)	(0.30)
2016E	-	-	-	-



SAGE Therapeutics is a biopharmaceutical company focused on developing drugs to treat CNS disorders where no effective options exist.

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# **Company Update**

# SAGE-547 Phase 3 design set, data possible 2H16

## Phase 3 trial to start mid-year 2015, crossover important

The phase 3 trial for SAGE-547 in super-refractory status epilepticus will be a randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of SAGE-547 (n = 126) vs. standard of care third-line anti-seizure agents, for a total of 6 days, and includes crossover, which should provide a definitive, unambiguous demonstration of efficacy. Similar to prior phase 1/2 studies, the primary endpoint will be successful resolution of status epilepticus (SE) confirmed via EEG after weaning the patient off all third-line anti-seizure agents, including SAGE-547 or placebo, without resumption of SE within 24 hours after drug administration. Additionally, patients who fail to respond to initial treatment (either SAGE-547 or placebo) may be eligible for crossover, with an open-label, higher-dose regimen of SAGE-547.

## Robust phase 3 design should provide clear, definitive evidence of success; data possible 2H16

We believe the phase 3 randomized, placebo-controlled trial design with crossover (rather than an open-label historical control study) will show definitive, unambiguous evidence of success for SAGE-547 vs. placebo for physicians and payors. Because SRSE patients are very complicated, with multiple co-morbidities and other medications, an open-label study may raise significant questions on the read-through to patients in real life, which we believe a randomized study design will address. Also, we believe the study design supports strong hospital uptake assuming positive results, since data should show a clear, definitive benefit vs. standard of care drugs, many of which are generic. We expect data to be presented 2H16, based on the company's 1-2 year estimate for n=100-200 patients.

## Additional open-label study for challenging SRSE interesting

SAGE is also conducting an additional open-label study in patients with SRSE who do not respond to conventional therapy outside of the phase 3 trial, which should add additional safety data. The trial will have the same dosing and procedural design as the phase 3 study, and include patients from sites that are already running the SAGE-547 emergency use trial, a positive in terms of a hasty accruement.

#### Final phase 2 SAGE-547 data at AED Trials XIII, May 13-15

SAGE will present more patients in its phase 1/2 clinical trial at the AED Trials XIII Conference on May 13-15, which we expect to show continued efficacy. Prior Phase 1/2 data in patients with SRSE showed that 71% of 17 evaluable patients met the primary endpoint of being successfully weaned off their anesthetic agents and also the study drug without SRSE recurrence. Importantly, most patients improved quickly (first five days of treatment), which we believe is meaningful since these patients are critically ill and have been in an anesthesia-induced coma for 11 days prior to treatment. We look forward to updated patient and safety data, especially on the higher SAGE-547 dose, and remain encouraged on the fact that none of the serious AEs noted in the study were related to drug.

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Figure 1: SAGE Income Statement

Revenues	2012A	2013A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
SAGE-547													
US			-	-		-	-	-	-	-	81,823	337,154	607,793
Ex-US			-					-		-	51,888	52,148	209,633
Ex-US roy alty									-	-	8,821	8,865	35,638
							_						
Total			-	-	-	-	-	-	-	-	90,644	346,019	643,431
Income Statement	2012A	2013A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
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Total Revenue COGS	-		-	•	•	•	· ·	-	-	-	90,644	346,019	643,431
	-	•	-		-	•	-	-	-	-	9,064	34,602	64,343
Gross Profit	-	-	-	•	-	-	-	-	-	-	81,580	311,417	579,088
Operating Expenses													
Research and development	7,229	14,357	24,100	9,520	10,302	12,333	14,312	46,467	48,697	45,016	45,294	51,970	61,438
General and administrative	2,402	3,922	9,710	1,862	1,880	1,899	1,918	7,559	7,687	7,764	32,806	35,706	38,893
Total Operating Expense	9,631	18,279	33,810	11,381	12,182	14,232	16,231	54,027	56,384	52,780	78,100	87,676	100,330
EBITDA													
Operating income	(9,631)	(18,279)	(33,810)	(11,381)	(12,182)	(14,232)	(16,231)	(54,027)	(56,384)	(52,780)	3,480	223,741	478,758
Interest (ex pense) income, net	_	1	8	4	8	4	8	24	8	24	8	24	8
Other income (expense), net	(1)	(3)	(9)	(3)	(9)	(3)	(9)	(24)	(9)	(24)	(9)	(24)	(9)
Pre-tax income (GAAP)	(9,632)	(18,281)	(33,811)	(11,380)	(12,183)	(14,231)	(16,232)	(54,027)	(56,385)	(52,780)	3,479	223,741	478,757
Pre-tax income (non-GAAP)					, , ,	, , ,	, , ,	,	,	, , ,			
Taxes (GAAP)						_	. •		_		1,287	82,784	177,140
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
		_											
Accretion of redeemable convertible preferred	(4)	(7)	(2,294)										
Net Income (GAAP)	(9,637)	(18,288)	(36,105)	(11,380)	(12,183)	(14,231)	(16,232)	(54,027)	(56,385)	(52,780)	2,192	140,957	301,617
GAAP EPS (diluted)	(\$8.62)	(\$12.26)	(\$1.67)	(\$0.23)	(\$0.24)	(\$0.27)	(\$0.30)	(\$1.04)	(\$1.06)	(\$0.90)	\$0.03	\$1.99	\$3.87
Diluted shares	1,118	1,492											
Pro forma - diluted shares		9,514	21,574	49,839	51,837	52,614	53,947	52,059	53,170	58,487	64,336	70,770	77,847

Source: Company Reports, Canaccord Genuity estimates



# Figure 2: SAGE Valuation

Product	Peak Sales / Royalties	Year	NPV at	Probability	Current Value	Value /
	(\$MM)	I cai	launch	Adjustment	(\$MM)	Share
SAGE-547						
US	\$984	2020	\$2,120	55%	\$886	\$33
Ex-US - roy alty	\$82	2024	\$184	55%	\$76	\$3
Total SAGE-547 revenues	\$1,066				\$963	
Total Product Value					963	\$36
Cash					149	\$6
Total Equity Value					1,112	\$41
Shares Outstanding (MM)					27	
Risk-Free Rate	3.0%					
Beta	1.8					
Risk Premium	4%					
Discount Rate	10%					

Valuation method	Value/share
Net Present Value	\$41
Price to Sales	\$75
Average	\$58

Source: Company Reports, Canaccord Genuity estimates



# Appendix: Important Disclosures

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#### **Target Price / Valuation Methodology:**

SAGE Therapeutics - SAGE

Our price target of \$58 is based on an average of our NPV and P/S valuations. Our NPV valuation estimates a \$41 value for the stock, and our P/S valuation estimates a \$75 value for the stock.

## Risks to achieving Target Price / Valuation:

SAGE Therapeutics - SAGE

Clinical trials for SAGE-547, 689, and 217 may ultimately fail, resulting in substantial downside to our estimates and price target. SAGE currently has no products approved by FDA or European regulatory agencies and has no revenues at present. Also, the exact number of patients suffering from super-refractory status epilepticus and other subsets of status epilepticus is not known. The actual number of SRSE patients may be smaller than modeled, which could result in difficulty enrolling clinical studies and longer clinical timelines. Smaller patient numbers could also result in lower revenues than our current estimates. Later-stage clinical trials for SAGE-547 may fail despite encouraging initial data from emergency use cases, resulting in lack of clinical approval, revenues, and downside to our price target. In addition, safety signals may emerge in Phase 1/2 and Phase 3 studies that were not seen in the initial emergency use cases. Safety signals could prevent FDA approval if serious. SAGE utilizes third parties, or clinical research organizations, to conduct its clinical studies for SAGE-547. Should these organizations conduct poor quality control, poor selection of clinical investigators, or improper statistical analysis, SAGE shares could be adversely impacted. Also, if the clinical research organization does not recruit the studies in a timely fashion, investors may become disappointed, creating downward pressure on the stock. Even assuming regulatory approval, SAGE's products may not perform well in the marketplace, resulting in lower revenues. If the pace of the launch is too slow. investors may be disappointed, and shares may be under pressure. Competitive products may emerge that generate better clinical data versus SAGE's pipeline. At present, SAGE's principal competitor is Marinus Pharmaceuticals, which is developing a reformulated form of Ganaxalone. a known GABA positive allosteric modulator neuroactive steroid, for potential treatment of drug-resistant partial complex seizures and fragile X syndrome. Also, many of SAGE's competitors have substantially more resources to fund clinical development, and may do so in a faster and/or more effective manner. SAGE is also likely to need substantial additional funding going forward, potentially creating downward pressure related to financing. Research and development costs may be higher than we have anticipated, requiring additional capital and potential dilution. SAGE expects to continue to incur substantial operating losses for the foreseeable future. The company may never become profitable, or profitability may take much longer than originally anticipated, disappointing some investors and resulting in downside to the share price.

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Global Stock Ratings (as of 04/02/15)

Rating	Coverag	Coverage Universe				
	#	%	%			
Buy	578	58.21%	33.22%			
Hold	327	32.93%	17.43%			
Sell	39	3.93%	0%			
Speculative Buy	49	4.93%	59.18%			
	993*	100.0%				

<sup>\*</sup>Total includes stocks that are Under Review

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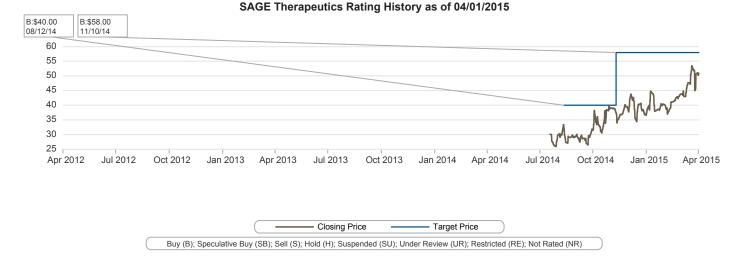
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