SAGE Therapeutics, Inc. (SAGE)

Q1 EPS: SAGE-547 Updated Data Bode Well for the Phase III Outlook

Buy

Price Target: $67.00
Prior: $67.00

What's Incremental

SAGE reported GAAP Q1 EPS of $(0.66), versus STRH at $(0.52) and cons. of $(0.49), due to higher OpEx from clinical ramp-up. Updated 547 Phase I/II results in SRSE detail 17/22, or 77% (previously 12/17 or 71%) response rates. We believe these impressive data provide a positive read through to the Phase III trial to start in mid-15. Phase III enrollment could be expedited as sites in the 302 study roll over. Follow-on drugs, SAGE-689 and SAGE-217, are on track to enter the clinic by YE15. We like SAGE into mid-15 data for 547 in essential tremor and postpartum depression - view them as upside.

Updated Phase I/II data for SAGE-547 continue to impress. SAGE announced updated Phase I/II data for SAGE-547 in super refractory status epilepticus (SRSE), to be presented on May 15th, at the Antiepileptic Drug and Device Trials XIII Conference. Of the 22 evaluable patients (vs. 17 previously), 16 were given low dose SAGE-547 (target plasma exposure 200 nM) and 6 were given high dose (target plasma exposure of 300 nM). 17 (77%) patients achieved the primary endpoint of successful weaning off general anesthesia and SAGE-547, as well as SRSE-free status in the 24-hour period post treatment (previously disclosed response rate was 71% in 17 evaluable patients). Observations through day 29 revealed that 4 (23%) out of the 17 responders experienced recurrent SE (1 patient in the 1-2 week period, 3 patients in the 3-4 week period). 14 patients were evaluated for continued EEG, and SAGE-547 administration resulted in peak (i.e. seizure) suppression, irrespective of the previous 3rd-line treatment regimen. Responders achieved clinically meaningful improvement on the Global Clinical Improvement Scale (CGI-S) and Glasgow Coma Scale (GCS) compared to non-responders. At day 29, responders had gained 3 points on the CGI-S (from most extremely ill/severely ill to mildly ill) versus 1 point improvement for non-responders. 7 responders achieved a full GCS score (no deficit) at day 29, versus 1 non-responder.

The SAGE-547 Phase III STATUS trial on track for a mid-15 start, the 302 trial should help ramp-up trial site onboarding. Management reiterated guidance that the Phase III STATUS (randomized, double-blind, placebo-controlled) study of SAGE-547 slated to enroll ~126 patients with SRSE aged 2 or older, at 150 sites (per management, >100 sites already reached out to SAGE). The primary endpoint is successful weaning from general anesthesia as well as SAGE-547/placebo and no SRSE recurrence within 24 hours post wean. Importantly, SE recurrence post the 24 hour period does not disqualify a patient from being counted as a responder (per SAGE, the FDA agreed that the primary endpoint is clinically meaningful for this very ill patient population, and benefit beyond 24 hours would be upside

Price (May 13, 2015)	$57.29
52-Wk Range	$62.06-$25.86
Market Cap ($M)	$1,478
ADTV	263,695
Shares Out (M)	25.8
Short Interest Ratio/% Of Float	6.3%
TR to Target	16.9%

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

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
Revenue ($M)					
FY	0	0	0	0	0
EPS Adjusted					
FY	(1.67)A	(2.83)	(2.52)	(3.15)	(2.86)
P/E	NM	NM		NM	
Consensus Rev					
FY	0	0	0	0	0
Consensus EPS Adjusted					
FY	(2.51)A	(2.09)	(2.09)	(2.44)	(2.44)
FYE Dec					

Salveen Richter, CFA
212-319-3728
salveen.richter@suntrust.com

Raluca Pancratov, Ph.D.
212-303-4178
raluca.pancratov@suntrust.com

SEE PAGE 6 FOR REQUIRED DISCLOSURE INFORMATION

to expectations). Non-responder patients are eligible for treatment with higher SAGE-547 dose (open label study portion). An open label Phase III study (302) enables treatment of SRSE patients currently not participating in the STATUS trial, and who cannot be transferred to a trial site (first patient treated as of 4/20/15). Recall that the time-limiting step for STATUS is study site onboarding. Management aims to expedite this step by potentially rolling 302 sites into the STATUS trial, and therefore accelerating patient enrollment (guidance unchanged for 1-2 years study duration). SAGE is comfortable with FDA interactions and is still exploring Breakthrough Designation (BTD), as a goal secondary to Phase III advancement. (Note, to date only 4/70 CNS products have been granted BTD, all had randomized clinical data).

Next up are SAGE-547 ET and PPD data, second generation molecules remain on track. We look towards readout of two proof-of-concept Phase II trials assessing SAGE-547 as a "probe molecule" for two indications in mid-15. For postpartum depression (PPD), SAGE is looking for activity in women who failed >1 SSRI (positive signals would be unequivocal responses on the Hamilton Rating Scale for Depression). SAGE-547 is evaluated in a double blind placebo controlled trial of essential tremor, and an activity signal would be patient response as measured by tremor amplitude. Both programs can thus be quickly stopped or expanded, as needed. SAGE-689 and SAGE-217 remain on track to enter the clinic by YE15, for adjunctive SRSE and orphan epilepsies (such as Dravet and Rett syndromes), respectively. A novel program (likely targeting NMDA) is still expected to be announced by YE15.

Changes to model post Q1 EPS: SAGE reported GAAP Q1 EPS of $(0.66), lower than consensus of $(0.49) and STRH at $(0.52). GAAP OpEx were $16.8M, exceeding our $13.3M estimate. GAAP R&D expense of $12.9M was above STRH of $9.5M (due to expenses related to clinical development of SAGE-547), while SG&A (GAAP) expense of $3.9M was in line with STRH of $3.8M. Stock based compensation expense was $1.3M. SAGE's cash reserves at the end of Q1 of $113M, in addition to $129.2M in net proceeds from a follow-on offering in April, are expected to provide runway through mid-2017. Per management, GAAP R&D is expected to be "choppy" in FY15, as stock based compensation levels reflect performance milestones and grants. Given the current OpEx trends and management commentary, we are significantly increasing our FY15+ OpEx estimates. In addition, given the increased share count post the secondary offering, our FY15 GAAP EPS estimate is now $(2.83) versus $(2.52) previously.

Figure 1: Q1/15 Variance Table

($thousands, except per share data)

	Mar Q1 2015A	Mar Q1 2015E	Variance A-E	Variance %	Y/Y %	Q/Q %
Revenue						
	-	-	-	N/A	N/A	N/A
Total Revenue	**$ -**	**$ -**	**$ -**	**N/A**	**N/A**	**N/A**
Operating expense						
R&D (GAAP)	12,900	9,542	3,358	26%	209%	44%
SG&A (GAAP)	3,997	3,812	185	5%	147%	17%
Stock-based compensation	1,300	-	1,300		-	
Other	-	-	-			
Total operating expense	16,897	13,354	3,543	21%	192%	37%
Operating income (loss)	(16,897)	(13,354)	(3,543)	21%	192%	37%
Other (expense) income, net	26	4	22	86%	-	2500%
Income Before Income Taxes	**(16,871)**	**(13,350)**	(3,521)	21%	191%	36%
Income Tax Provision	-	-	-			
Net loss applicable to common shareholders	**$ (16,871)**	**$ (13,350)**	(3,521)	21%	176%	36%
GAAP EPS (diluted)	**$ (0.66)**	**$ (0.52)**	(0.14)	21%	-44%	36%
Weighted shares outstanding basic and diluted - GAAP	25,655	25,736	(81)	0%	393%	0%

Source: STRH analysis and Company reports

Figure 2: Upcoming Expected Milestones

Product	Timing	Indication	Event
SAGE-547	**May 15, Antiepileptic Drug and Device Trials**	**Super refractory status epilepticus (IV)**	**Announce final data from a Phase I/II trial**
SAGE-547	**By mid-2015**	**Post-partum Depression**	**Phase II topline data**
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
Likely NMDA modulator	Late-2015	Undisclosed orphan indication	Announce next program

Source: STRH analysis and Company reports

Sage Therapeutics

(NASDAQ: SAGE)

Salveen Richter, CFA
(212) 319-3728
salveen.richter@suntrust.com

Consolidated Income Statement

($thousands, except per share data)	FY 2012A	FY 2013A	FY 2014A	Mar Q1 2015A	Jun Q2 2015E	Sep Q3 2015E	Dec Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Revenue													
SAGE-547	$ -	$ -	$ -	-	-	-	-	$ -	$ -	$ -	$ 63,810	$ 332,738	$ 545,591
Total Revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 332,738	$ 545,591
COGS	-	-	-	-	-	-	-	-	-	-	5,105	36,601	60,015
Gross profit	-	-	-	-	-	-	-	-	-	-	58,705	296,137	485,576
Operating expense													
R&D (GAAP)	7,229	14,357	24,100	12,900	14,412	15,003	16,002	58,317	70,223	80,232	90,152	100,242	110,532
SG&A (GAAP)	2,402	3,922	9,710	3,997	5,002	5,157	6,002	20,158	30,122	50,033	82,823	90,232	100,213
Total operating expense	9,631	18,279	33,810	16,897	19,414	20,160	22,004	78,475	100,345	130,265	172,975	190,474	210,745
Operating income (loss)	**(9,631)**	**(18,279)**	**(33,810)**	**(16,897)**	**(19,414)**	**(20,160)**	**(22,004)**	**(78,475)**	**(100,345)**	**(130,265)**	**(114,270)**	**105,663**	**274,831**
Interest Income (expense), net	-	1	8	21	50	85	96	252	65	85	87	115	230
Other income (expense), net	(1)	(3)	(9)	5	-	-	-	5	5	10	20	40	75
Total Other Income	(1)	(2)	(1)	26	50	85	96	257	70	95	107	155	305
Income before income taxes	(9,632)	(18,281)	(33,811)	(16,871)	(19,364)	(20,075)	(21,908)	(78,218)	(100,275)	(130,170)	(114,162)	105,818	275,136
Provision for income taxes	-	-	-	-	-	-	-	-	-	-	-	5,291	27,514
Net gain (loss)	**(9,632)**	**(18,281)**	**(33,811)**	**(16,871)**	**(19,364)**	**(20,075)**	**(21,908)**	**(78,218)**	**(100,275)**	**(130,170)**	**(114,162)**	**100,527**	**247,623**
Accretion of redeemable convertible preferred stock	(4)	(7)	(2,294)										
Net gain (loss) applicable to common shareholders	**$ (9,636)**	**$ (18,288)**	**$ (36,105)**	**$ (16,871)**	**$ (19,364)**	**$ (20,075)**	**$ (21,908)**	**$ (78,218)**	**$ (100,275)**	**$ (130,170)**	**$ (114,162)**	**$ 100,527**	**$ 247,623**
GAAP EPS (diluted)	**$ (2.74)**	**$ (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)	3,522,607	1,492	21,574	25,655	27,805	28,551	28,694	27,676	31,838	32,989	35,472	39,029	40,980
		$ 4											
Margin Analysis:													
Cost of product sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	8%	11%	11%
Product gross margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	92%	89%	89%
R&D (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	141%	30%	20%
SG&A (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	130%	27%	18%
Stock-based compensation expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	0%	0%
Total operating expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	271%	57%	39%
Operating margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-179%	32%	50%
Income tax provision	N/A	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	5%	10%
Net margin (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-179%	30%	45%
Y/Y change:													
Total revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	521%	164%
SAGE-547 revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	521%	164%
R&D (GAAP)	N/A	99%	68%	209%	229%	127%	79%	142%	20%	14%	12%	11%	10%
SG&A (GAAP)	N/A	63%	148%	147%	177%	80%	76%	108%	49%	66%	66%	9%	11%
Stock-based compensation expense	N/A	N/A	N/A	650%	0%	0%	0%	0%	N/A	N/A	N/A	N/A	N/A
Total operating expense	N/A	90%	85%	192%	214%	113%	78%	132%	28%	30%	33%	10%	11%
Operating income	N/A	90%	85%	192%	214%	113%	78%	132%	28%	30%	-12%	-192%	160%
Net income (GAAP)	N/A	90%	97%	176%	149%	104%	77%	117%	28%	30%	-12%	-188%	146%
GAAP EPS (diluted)	N/A	348%	-86%	-44%	-85%	40%	58%	-69%	-11%	-25%	18%	180%	-135%
Shares outstanding - GAAP	N/A	-100%	1346%	393%	1535%	46%	12%	28%	15%	4%	8%	10%	5%

Source: STRH Research, Company Reports

Revision Table

($thousands, except per share data)	FY15E		FY16E		FY17E		FY18E		FY19E		FY20E	
	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior
Revenue												
SAGE-547	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 63,810	$ 332,738	$ 332,738	$ 545,591	$ 545,591
SAGE-689	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
SAGE-217	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Undisclosed NMDA Program	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total Revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 63,810	$ 332,738	$ 332,738	$ 545,591	$ 545,591
COGS	-	-	-	-	-	-	5,105	5,105	36,601	36,601	60,015	60,015
Gross profit	-	-	-	-	-	-	58,705	58,705	296,137	296,137	485,576	485,576
Operating expense												
R&D (GAAP)	58,317	46,802	70,223	60,221	80,232	70,224	90,152	80,334	100,242	90,211	110,532	100,260
SG&A (GAAP)	20,158	18,557	30,122	23,556	50,033	48,910	82,823	74,002	90,232	79,043	100,213	84,056
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	-	-
Total operating expense	78,475	65,359	100,345	83,777	130,265	119,134	172,975	154,336	190,474	169,254	210,745	184,316
Operating income (loss)	**(78,475)**	**(65,359)**	**(100,345)**	**(83,777)**	**(130,265)**	**(119,134)**	**(114,270)**	**(95,631)**	**105,663**	**126,883**	**274,831**	**301,260**
Interest Income (expense), net	252	17	65	35	85	56	87	60	115	93	230	215
Other income (expense), net	5	-	5	-	10	-	20	-	40	-	75	-
Other (expense) income, net	257	17	70	35	95	56	107	60	155	93	305	215
Income before income taxes	(78,218)	(65,342)	(100,275)	(83,742)	(130,170)	(119,078)	(114,162)	(95,571)	105,818	126,976	275,136	301,475
Provision for income taxes	-	-	-	-	-	-	-	-	**5,291**	**12,698**	**27,514**	**30,147**
Net gain (loss)	(78,218)	(65,342)	(100,275)	(83,742)	(130,170)	(119,078)	(114,162)	(95,571)	100,527	114,278	247,623	271,327
Accretion of redeemable convertible preferred stock	-	-	-	-	-	-	-	-	-	-	-	-
Net loss applicable to common shareholders	$ (78,218)	$ (65,342)	$ (100,275)	$ (83,742)	$ (130,170)	$ (119,078)	$ (114,162)	$ (95,571)	$ 100,527	$ 114,278	$ 247,623	$ 271,327
GAAP EPS (diluted)	$ (2.83)	$ (2.52)	$ (3.15)	$ (2.85)	$ (3.95)	$ (3.90)	$ (3.22)	$ (2.90)	$ 2.58	$ 3.14	$ 6.04	$ 7.11
Weighted shares outstanding basic and diluted	27,676	25,930	31,838	29,432	32,989	30,559	35,472	32,921	39,029	36,350	40,980	38,167

Source: STRH Research, Company Reports

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. Its 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. The company'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 drug 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 tackle 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 wings (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 $67 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes $53.49/share to SAGE-547 U.S. sales, $8.76 to SAGE-547 E.U. sales, $0.62 to SAGE-547 ROW sales, and $4.38/share to cash. We assign SAGE-547 in 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 12% 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 71-78% 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 30-50% 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 1 month after wean. We expect clarity on this endpoint in Q1 2015, when SAGE communicates the results of their end-of-Phase II meeting with FDA.

- **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

Companies Mentioned in This Note

SAGE Therapeutics, Inc. (SAGE, $57.29, Buy)

Analyst Certification

I, Salveen Richter , 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

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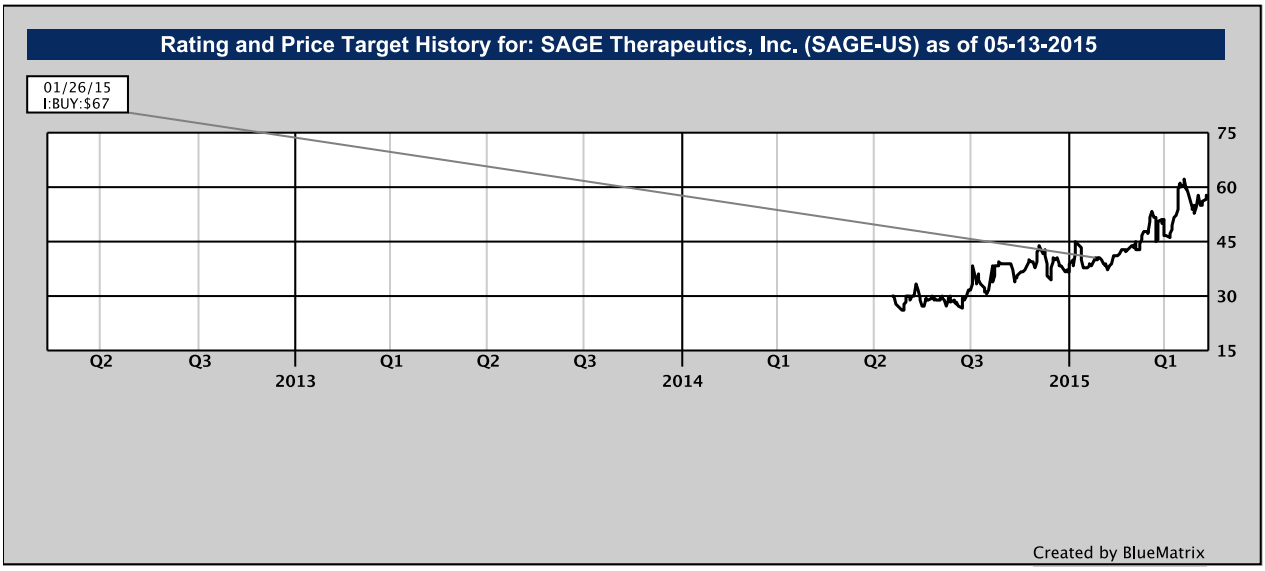

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*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
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D = drop coverage
I = initiate coverage
T = transfer coverage

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