

SAGE Therapeutics

SAGE : NASDAQ : US\$38.80

BUY

Target: US\$58.00

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COMPANY STATISTICS:

Forecast Return: 49%
 Market Cap (M): US\$930
 52-week Range: 24.25 - 41.01
 Avg. Daily Vol. (000s): 145.5

EARNINGS SUMMARY:

FYE Dec	2014E	2015E	2016E
P/Sales:	NM	NM	NM
P/E:	NM	NM	NM
Revenue (M):			
Q1	0.0A	0.0	--
Q2	0.0A	0.0	--
Q3	0.0	0.0	--
Q4	0.0	0.0	--
Total	0.0	0.0	0.0
EPS:			
Q1	(3.70)A	(0.39)	--
Q2	(4.57)A	(0.35)	--
Q3	(0.30)	(0.37)	--
Q4	(0.42)	(0.40)	--
Total	(1.84)	(1.51)	(1.54)

SHARE PRICE PERFORMANCE:



Source: Interactive Data Corporation

COMPANY DESCRIPTION:

SAGE Therapeutics is a development/clinical stage biopharmaceutical company founded in 2010 that is focused on developing and commercializing drugs to treat central nervous system (CNS) disorders where no effective or FDA approved options exist.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

SAGE-547 PH2 DATA POSITIVE, MAINTAINED REMISSION OF SRSE AFTER WEANING OFF STUDY DRUG

Investment highlights

73% overall response rate in critically ill patients

SAGE-547 showed 8/11 evaluable patients with super-refractory status epilepticus (SRSE) met the primary endpoint of being successfully weaned off of anesthesia (73% response rate), which we believe is very impressive given the strict definition of response in which only one weaning attempt is allowed. One patient was excluded due to death from unrelated causes (toxic overdose from suicide attempt), which we believe is reasonable.

No recurrence of SRSE after weaned off SAGE-547, positive

Importantly, out of the 8 patients that met the primary endpoint, none of these patients had a recurrence of SRSE for 48 hours when weaned from SAGE-547. We believe this resonates very positively with ICU specialists in transferring these patients out of the ICU. SAGE is expected to report further data on 30-day SRSE recurrence follow-up by YE14, although the company states that many patients maintained remission beyond the 48-hour period.

Positive safety and tolerability data vs. conventional therapy

All patients tolerated SAGE-547 without drug-related serious adverse events, which we believe is important given the fact that current treatment available contains high toxicity. All anesthesia, including midazolam, propofol and barbituates, are clouded by severe side effects including hypotension, cardiorespiratory depression and pancreatitis, for instance. We believe this clean side effect profile simplifies the risk vs. benefit decision for physicians, with specialists potentially prescribing the drug in an earlier setting.

FDA end of Phase 2 meeting YE14, expect trial start 1H15

SAGE has an end of Phase 2 meeting scheduled with FDA, which we expect to occur by YE14, and include discussion of a Phase 3 trial, which SAGE expects to initiate during 1H15. We believe that a placebo controlled design for Phase 3 is very feasible if performed, but we await further details from SAGE following the end of Phase 2 meeting with FDA.

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10 November 2014

Figure 1: SAGE valuation – average of NPV and P/S

Valuation method	Value/share
Net Present Value	\$40
Price to Sales	\$75
Average	\$58

Source: Canaccord Genuity estimates

Figure 2: SAGE NPV valuation

Product	Peak Sales / Royalties (\$MM)	Year	NPV at launch	Probability Adjustment	Current Value (\$MM)	Value / Share
SAGE-547						
US	\$984	2020	\$2,148	55%	\$864	\$32
Ex-US - royalty	\$82	2024	\$177	55%	\$71	\$3
Total SAGE-547 revenues	\$1,066				\$935	
Total Product Value					935	\$35
Cash					149	\$6
Total Equity Value					1,084	\$40
Shares Outstanding (MM)					27	
Risk-Free Rate		3.0%				
Beta		1.8				
Risk Premium		4%				
Discount Rate		10%				

Source: Canaccord Genuity estimates

Figure 3: SAGE P/S valuation

Product	Peak revenues	Year	probability	P/S	Value / share
SAGE-547					
US	\$984	2020	55%	6	66
Ex-US	\$82	2024	55%	6	4
Total Product Value					\$70
Cash					\$6
Total Equity Value					\$75
Shares Outstanding (MM)					27
Risk-Free Rate		3.0%			
Beta		1.8			
Risk Premium		4%			
Discount Rate		10%			

Source: Canaccord Genuity Estimates

10 November 2014

Figure 4: SAGE income statement

	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues													
SAGE-547													
US							-	-	-	-	81,823	337,154	607,793
Ex-US							-	-	-	-	51,888	52,148	209,633
Ex-US royalty									-	-	8,821	8,865	35,638
Total			-	-	-	-	-	-	-	-	90,644	346,019	643,431
Income Statement	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue	-	-	-	-	-	-	-	-	-	-	90,644	346,019	643,431
COGS	-	-	-	-	-	-	-	-	-	-	9,064	34,602	64,343
Gross Profit	-	-	-	-	-	-	-	-	-	-	81,580	311,417	579,088
Operating Expenses													
Research and development	7,229	14,357	4,173	4,381	6,325	9,747	24,626	39,236	41,689	42,996	47,760	57,785	71,508
General and administrative	2,402	3,922	1,617	1,807	1,825	1,843	7,092	7,559	7,687	7,764	32,806	35,706	38,893
Total Operating Expense	9,631	18,279	5,790	6,188	8,150	11,591	31,718	46,795	49,376	50,760	80,565	93,491	110,401
EBITDA													
Operating income	(9,631)	(18,279)	(5,790)	(6,188)	(8,150)	(11,591)	(31,718)	(46,795)	(49,376)	(50,760)	1,015	217,926	468,687
Interest (expense) income, net	-	1	-	1	1	1	3	8	3	8	3	8	3
Other income (expense), net	(1)	(3)	-	(5)	(5)	(5)	(15)	(40)	(15)	(40)	(15)	(40)	(15)
Pre-tax income (GAAP)	(9,632)	(18,281)	(5,790)	(6,192)	(8,154)	(11,595)	(31,730)	(46,827)	(49,388)	(50,792)	1,003	217,894	468,675
Pre-tax income (non-GAAP)													
Taxes (GAAP)	-	-	-	-	-	-	-	-	-	-	371	80,621	173,410
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Accretion of redeemable convertible preferred	(4)	(7)	(326)	(1,577)									
Net Income (GAAP)	(9,637)	(18,288)	(6,116)	(7,769)	(8,154)	(11,595)	(33,633)	(46,827)	(49,388)	(50,792)	632	137,273	295,265
GAAP EPS (diluted)	(\$8.62)	(\$12.26)	(\$3.70)	(\$4.57)	(\$0.30)	(\$0.42)	(\$1.84)	(\$1.51)	(\$1.54)	(\$1.44)	\$0.02	\$3.21	\$6.29
Diluted shares	1,118	1,492	1,653										
Pro forma - diluted shares		9,514	16,774	1,701	27,270	27,543	18,322	30,973	32,084	35,292	38,821	42,703	46,974
Pro forma EPS (diluted)		(\$1.92)	(\$0.36)	(\$4.57)	(\$0.30)	(\$0.42)	(\$1.84)	(\$1.51)	(\$1.54)	(\$1.44)	\$0.02	\$3.21	\$6.29

Source: Company reports, Canaccord Genuity estimates

Investment risks

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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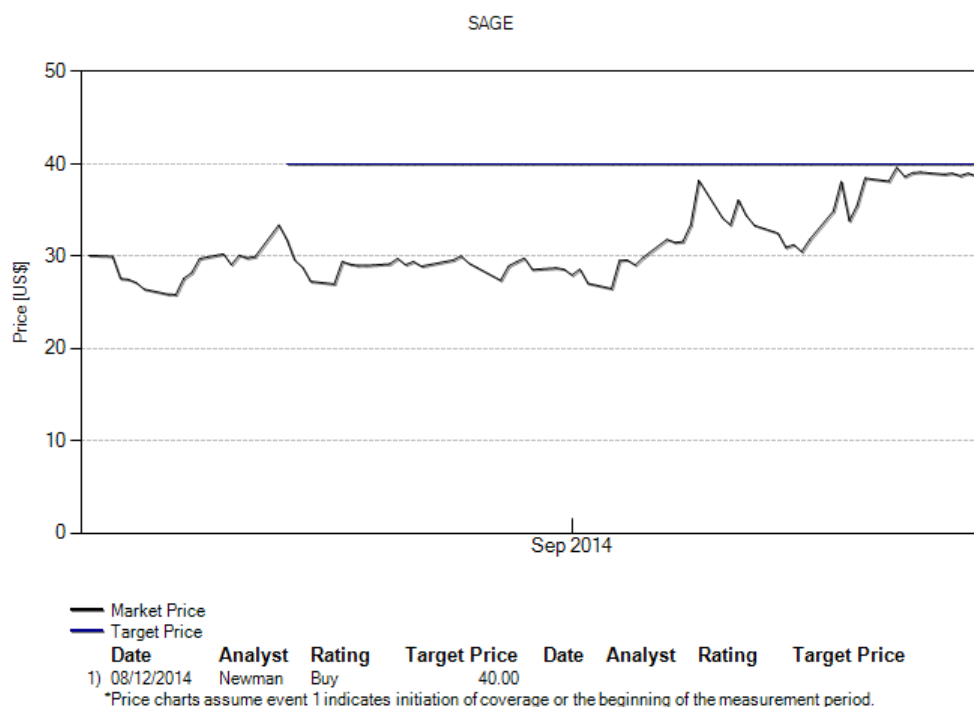
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Site Visit:

An analyst has not visited SAGE Therapeutics' material operations.

Price Chart:***Distribution of Ratings:**

Global Stock Ratings
(as of 1 October 2014)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	627	60.2%	36.7%
Speculative Buy	53	5.1%	54.7%
Hold	317	30.5%	13.9%

Sell	43	4.1%	2.3%
	1041	100.0%	

*Total includes stocks that are Under Review

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