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SAGE Therapeutics

Biotechnology

US Equity Research
27 February 2015

BUY
unchanged

PRICE TARGET US$58.00
unchanged

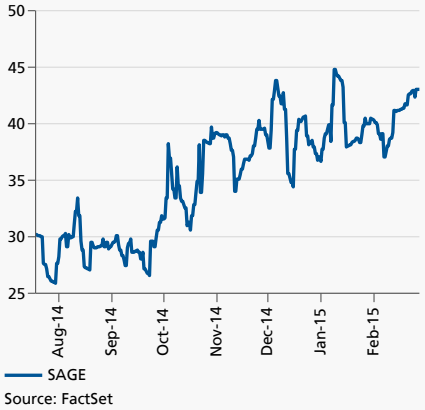
Price (27-Feb)	US$42.99
Ticker	SAGE-NASDAQ

52-Week Range (US$):	24.25 - 47.76
Avg Daily Vol (M) :	145.7
Shares Out. (M) :	24.0
Market Cap (US$M):	1,030

FYE Dec	2014A	2015E	2016E
Sales (US$M)	0.0	0.0	0.0
EPS Adj&Dil (US$)	(1.67)↑	(1.04)↑	(1.06)↑
Previous	*(1.84)*	*(1.51)*	*(1.54)*

Quarterly Sales	Q1	Q2	Q3	Q4
2014A	0.0	0.0	0.0	0.0
2015E	0.0	0.0	0.0	0.0
2016E	-	-	-	-

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2014A	(3.70)	(4.57)	(0.50)	(0.26)
2015E	(0.23)	(0.24)	(0.27)	(0.30)
2016E	-	-	-	-



Source: FactSet

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

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Estimates Revised

Expect final Phase 1/2 SAGE-547 data midyear, Phase 3 design 1Q15, Phase 2 tremor, PPD data 2Q15

SAGE-547 final data expected mid-2015

We expect final Phase 1/2 data for SAGE-547 as adjunctive therapy for the treatment of SRSE by mid-2015, which should move shares higher. We remind investors that these patients are critically ill, with the mean duration of status epilepticus prior to treatment of 11 days. To date, seventeen (71%) of twenty Super-Refractory Status Epilepticus (SRSE) patients on study drug were able to be weaned off of anesthesia-induced coma without recurrence of SRSE, with improvements seen as quickly as the first five days, which we believe is very positive. Additionally, the SAGE-547 emergency use program continues to validate the efficacy of the drug, demonstrating an impressive 78% overall response rate, giving us confidence in the drug as it moves into pivotal studies.

Initiation of Phase 3 registration study mid-2015

SAGE will provide details on the Phase 3 design by end of 1Q15, based on discussions with FDA, and plans to initiate the trial by mid-2015. We believe Phase 3 data could surface by YE16 or earlier, since the Phase 3 trial will use most of the sites from the prior Phase 1/2 study. We expect the study to be placebo controlled, and believe crossover may be allowed based on the severity of SRSE. The Phase 3 controlled study design is consistent with guidance from SAGE, and we do not believe investors were expecting filing based on the Phase 1/2 and emergency use data alone.

Proof of concept data in CNS disorders may surprise

Phase 2 data for SAGE-547 in Essential Tremor (ET) and severe PostPartum Depression (PPD) are expected by mid-2015, which may be interesting. Although both studies are primarily studying PK and safety, the trial will report outcome measures, with tremors measured by the accelerometer and PPD by the HAM-D-17 and CGI-I scale, which may be a catalyst for the stock if results show early signs of efficacy

Second generation molecules to enter clinic YE15

We expect SAGE-689 (second-line therapy for refractory status epilepticus) to enter Phase 1 by YE15, addressing a significantly larger patient population since it will be used in earlier emergency room settings. Additionally, we expect initiation of a Phase 1 study for SAGE-217 (oral therapy for seizures) also by YE15 in orphan genetic epilepsies, which may include Dravet Syndrome, Rett Syndrome, or Fragile X.

Maintain BUY, $58 PT

We maintain our BUY rating and $58 price target. We change our 2015 EPS estimates to $(1.04) from $(1.51) based on 4Q14 company updates. We have raised our R&D expense in 2015 to reflect initiation of a Phase 3 study for 547 as well as the ongoing hase 2 studies in ET and PPD.

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 royalty									-	-	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
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	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 (expense) 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
Pro forma EPS (diluted)		**($1.92)**	**($1.67)**	**($0.23)**	**($0.24)**	**($0.27)**	**($0.30)**	**($1.04)**	**($1.06)**	**($0.90)**	**$0.03**	**$1.99**	**$3.87**

Source: Company reports, Canaccord Genuity estimates

Figure 2: SAGE valuation

Product	Peak Sales / Royalties ($MM)	Year	NPV at launch	Probability Adjustment	Current Value ($MM)	Value / Share
SAGE-547						
US	$984	2020	$2,120	55%	$878	$33
Ex-US - royalty	$82	2024	$183	55%	$75	$3
Total SAGE-547 revenues	$1,066				$953	
Total Product Value					953	$35
Cash					149	$6
Total Equity Value					**1,102**	**$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**

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: Company reports, Canaccord Genuity estimates

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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 $40 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.

Distribution of Ratings:

Global Stock Ratings (as of 02/27/15)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	573	58.00%	33.86%
Hold	327	33.10%	17.13%
Sell	40	4.05%	2.50%
Speculative Buy	48	4.86%	56.25%
	988*	100.0%	

*Total includes stocks that are Under Review

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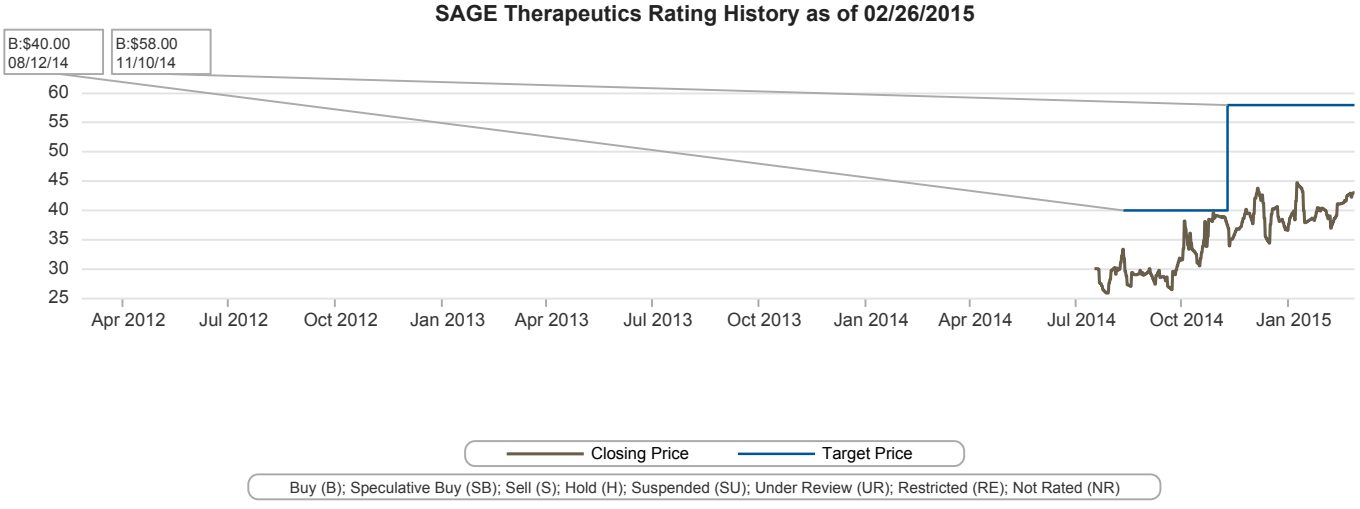

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