SAGE Therapeutics

Biotechnology

US Equity Research
10 June 2015

BUY
unchanged

PRICE TARGET	US$110.00↑
from US$85.00	
Price (9-Jun)	US$86.71
Ticker	SAGE-NASDAQ

52-Week Range (US$):	24.25 - 81.20
Avg Daily Vol (M) :	197.1
Shares Out. (M) :	21.6
Market Cap (US$M):	1,871

FYE Dec	2014A	2015E	2016E
Sales (US$M)	0.0	0.0	0.0
EPS Adj&Dil (US$)	(1.67)	(2.56)	(2.42)

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	(0.66)	(0.58)	(0.64)	(0.68)
2016E	-	-	-	-

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

John Newman, PhD | Canaccord Genuity Inc. (US) | JNewman@canaccordgenuity.com | 212.389.8042
Kevin Dai, PharmD, BCOP | Canaccord Genuity Inc. (US) | kdai@canaccordgenuity.com | 212.389.8043

Raising Target Price

SAGE-547 positive in postpartum depression, supports additional indications; raising PT to $110 from $85

SAGE-547 demonstrates statistical improvement in postpartum depression (PPD)

SAGE announced positive top-line data from their exploratory clinical trial in improving postpartum depression (PPD), suggesting 547 and follow-on drugs will be active in indications outside of Status Epilepticus. The PPD data showed improvement in four women that failed prior antidepressants within 24 hours after administration of IV SAGE-547, a positive in demonstrating early proof of concept (POC) of this new indication for the company's compound. As measured by the Hamilton Rating Scale for Depression (HAM-D), where a score above 24 is considered severe depression and scores <7 are symptom free, the patients improved to a mean HAM-D score of 1.8 after the 60-hour treatment from 26.5, which we believe is both statistically and clinically positive. Additionally, the company states there is consistent improvements in the Clinical Global Impression-Improvement (CGI-I) scale. Based on the small/early positive data seen in PPD, the company will begin an open-label exploratory trial with a placebo arm in PPD by YE15, with positive data likely to be a catalyst for the stock.

Safety clean for SAGE-547, sedation main side effect observed

SAGE-547 was well-tolerated in the treated patients, with no discontinuations seen due to adverse events, a positive. Although a total of 14 adverse events were observed in the n=4 patients, only sedation was seen in two. All the side effects were mild to moderate and were self limiting, which we believe is positive going into larger studies.

Look for POC in ET by mid-2015 and data in wholly-owned compounds by 2016 to drive shares

We continue to anticipate Phase 2 data for SAGE-547 in Essential Tremor (ET)) by mid-2015, but may see a more modest efficacy signal given dose escalation may be needed. Additionally, we look forward to updates from the company's wholly-owned assets (SAGE-689 for adjunctive IV therapy for status epilepticus and SAGE-217 as an oral therapy for orphan epilepsies) in 2016 to drive shares prior to phase 3 data for the STATUS trial. We believe the company is set up well with multiple catalysts in 2015-2016, making the stock a strong buying opportunity ahead of the main phase 3 data for SAGE-547 in super-refractory status epilepticus (SRSE).

Maintain BUY, increasing PT to $110

We maintain our BUY rating and increase our PT to $110 from $85. We include PPD in our valuation, which we expect to peak at $53M in the US by 2025, and assume a 30% probability of approval. Additional, we increase our P/S multiple from 6 to 6.5 given the positive momentum of the company, expecting additional data in new wholly owned compounds by early next year, and expected positive data for their pivotal phase 3 trial in status epilepsy for SAGE-547 by mid-2016, which increases our PT to $110.

Estimate $53M peak sales by 2025

CDC reports ~ 11-20% of women who give birth have post-partum depression (PPD). With an average of four million women in the US giving birth a year and assuming an average 15%, we believe that there are ~600,000 women with PPD per year. However, there are about 2 million women who miscarry or whose babies are stillborn, and these women are also susceptible to postpartum depression (sometimes even higher than the initial 15%). Therefore, we believe that the US incidence of PPD is ~ 1M patients per year.

Out of the ~1M PPD patients, we believe only 15% of patients actually seek pharmacological treatment, but ramp this up slowly to 20% as more treatments become available to patients. Therefore, we estimate ~200,000 – 210,000 patients by 2025. According to clinical trials with conventional antidepressants, large, randomized, double-blind studies showed response rates of ~50-60% with sertraline and nortriptyline. Therefore, we assume that 40% of patients will be refractory to initial antidepressants, leaving ~80,000 – 85,000 patients by 2025. We give 20% peak share for SAGE-547 by 2025. Additionally, we assume a price of ~$500 a month (premium to current branded antidepressants of ~200/month), an annualized 2.5% price increase, 9-11 month duration of therapy (Epperson et al. *AFFP. 1999),* and a 50% compliance rate, and a 6% discount and rebate on the final revenue to reach peak sales of $53M by 2025.

Ex-US royalties to peak at $9M

For ex-US sales, we believe there are 50% more PPD patients due to the larger demographics in EU vs. US. We assume the same clinical assumptions as US, but a 25% discount to the US price, leaving us with ~$49M in peak sales by 2025. Assuming the company will partner ex-US for this product and garner a 20% royalty, we assume peak royalties to be ~$9M by 2025.

Figure 1: SAGE-547 in PPD

Postpartum Depression	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
US Market											
Incidence - Non-hospital	**1,000,000**	**1,005,000**	**1,010,025**	**1,015,075**	**1,020,151**	**1,025,251**	**1,030,378**	**1,035,529**	**1,040,707**	**1,045,911**	**1,051,140**
% women receiving treatment	15%	15%	15%	15%	15%	17%	17%	19%	20%	20%	20%
PPD patients receiving Rx treatmen	**150,000**	**150,750**	**151,504**	**152,261**	**153,023**	**174,293**	**175,164**	**196,751**	**208,141**	**209,182**	**210,228**
% failing antidepressants	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
PPD patients requiring 2nd line tx	**60,000**	**60,300**	**60,602**	**60,905**	**61,209**	**69,717**	**70,066**	**78,700**	**83,257**	**83,673**	**84,091**
SAGE-547 %				2%	4%	5%	7%	10%	12%	17%	20%
Patients receiving SAGE 547	**-**	**-**	**-**	**1,218**	**2,448**	**3,486**	**4,905**	**7,870**	**9,991**	**14,224**	**16,818**
Cost month			$500	$513	$525	$538	$552	$566	$580	$594	$609
Number of months			9	9	9	9	10	10	11	11	11
Compliance				50%	50%	50%	50%	50%	50%	50%	50%
Cost per patient	**-**	**-**		**2,306**	**2,364**	**2,423**	**2,760**	**2,829**	**3,189**	**3,269**	**3,351**
SAGE-547 revenues											
SAGE-547 demand ($000's)	-	-	-	2,809	5,788	8,446	13,534	22,261	31,862	46,498	56,351
Inventory build / (drawdown)											
Discounts & rebates		$ -	$	(169)	$ (347)	$ (507)	$ (812)	$ (1,336)	$ (1,912)	$ (2,790)	$ (3,381)
US SAGE-547 revenues ($000's)	**-**	**-**	**-**	**2,641**	**5,440**	**7,939**	**12,722**	**20,925**	**29,950**	**43,708**	**52,970**

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Postpartum Depression	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Ex-US Market											
Incidence - Non-hospital	**1,500,000**	**1,507,500**	**1,515,038**	**1,522,613**	**1,530,226**	**1,537,877**	**1,545,566**	**1,553,294**	**1,561,061**	**1,568,866**	**1,576,710**
% women receiving treatment	15%	15%	15%	15%	15%	17%	17%	19%	20%	20%	20%
PPD patients receiving Rx treatmen	**225,000**	**226,125**	**227,256**	**228,392**	**229,534**	**261,439**	**262,746**	**295,126**	**312,212**	**313,773**	**315,342**
% failing antidepressants	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
PPD patients requiring 2nd line tx	**90,000**	**90,450**	**90,902**	**91,357**	**91,814**	**104,576**	**105,099**	**118,050**	**124,885**	**125,509**	**126,137**
SAGE-547 %				2%	4%	5%	7%	10%	12%	17%	20%
Patients receiving SAGE 547	**-**	**-**	**-**	**1,827**	**3,673**	**5,229**	**7,357**	**11,805**	**14,986**	**21,337**	**25,227**
Cost month			$375	$375	$375	$375	$375	$375	$375	$375	$375
Number of months			9	9	9	9	10	10	11	11	11
Compliance				50%	50%	50%	50%	50%	50%	50%	50%
Cost per patient	**-**	**-**		**1,688**	**1,688**	**1,688**	**1,875**	**1,875**	**2,063**	**2,063**	**2,063**
SAGE-547 revenues											
SAGE-547 demand ($000's)	-	-	-	3,083	6,197	8,824	13,794	22,134	30,909	44,007	52,031
Inventory build / (drawdown)											
Discounts & rebates		$ -	$	(185)	$ (372)	$ (529)	$ (828)	$ (1,328)	$ (1,855)	$ (2,640)	$ (3,122)
US SAGE-547 revenues ($000's)	**-**	**-**	**-**	**2,898**	**5,826**	**8,294**	**12,967**	**20,806**	**29,054**	**41,366**	**48,910**

Source: Company reports, Canaccord Genuity estimates

Figure 2: SAGE valuation

Product	Peak revenues	Year	probability	P/S	Value / share
SAGE-547 SRSE					
US	$984	2020	70%	7	98
Ex-US	$82	2024	70%	7	5
SAGE-547 PPD					
US	$53	2025	30%	7	1
Ex-US	$9	2025	30%	7	0
Total Product Value					$104
Cash					$6
Total Equity Value					**$110**
Shares Outstanding (MM)					25

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	4%
Discount Rate	11%

Source: Company reports, Canaccord Genuity estimates

Figure 3: SAGE income statement

Revenues	2012A	2013A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
SAGE-547 SRSE													
US			-	-	-	-	-	-	-	-	81,823	337,154	607,793
Ex-US			-					-	-	-	51,888	52,148	209,633
Ex-US royalty									-	-	8,821	8,865	35,638
SAGE-547 PPD													
US			-	-	-	-	-	-	-	-	2,641	5,440	7,939
Ex-US			-					-	-	-	2,898	5,826	8,294
Ex-US royalty											524	1,054	1,500
Total			-	-	-	-	-	-	-	-	**93,809**	**352,513**	**652,870**

Income Statement	2012A	2013A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue	-	-	-	-	-	-	-	-	-	-	93,809	352,513	652,870
COGS	-	-	-	-	-	-	-	-	-	-	9,381	35,251	65,287
Gross Profit	-	-	-	-	-	-	-	-	-	-	84,428	317,261	587,583
Operating Expenses													
Research and development	7,229	14,357	24,100	12,900	15,003	17,152	19,254	64,309	64,505	57,323	55,439	62,278	72,142
SAGE-547	125	3,918	9,707	4,885	9,771	11,744	13,736	40,136	40,939	28,657	20,060	18,054	16,249
SAGE-689	1,047	2,772	4,620	1,570	1,805	1,895	1,914	7,184	7,903	10,669	14,403	19,444	26,249
SAGE-217	-	1,129	3,524	1,172	1,231	1,243	1,256	4,902	5,883	7,647	9,942	12,924	16,801
other r&d	3,495	3,388	231	(14)	(15)	(15)	(15)	(59)	(64)	(71)	(78)	(86)	(94)
Options expense				600	600	600	600	2,400	2,880	3,456	4,147	4,977	5,972
Unallocated expenses	2,562	3,150	6,018	1,907	1,610	1,685	1,763	6,965	6,965	6,965	6,965	6,965	6,965
Personnel related expenses	2,116	2,718	4,685	1,214	1,456	1,529	1,606	5,805	1,622	5,863	1,638	5,922	1,654
Other expenses	446	432	531	152	154	156	157	619	159	625	160	632	162
General and administrative	2,402	3,922	9,710	3,997	4,216	4,369	4,529	17,111	15,139	15,290	40,319	44,088	48,231
Personnel related	899	1,764	3,133	2,798	2,910	3,055	3,208	11,971	12,270	12,393	37,393	41,132	45,246
Professional fees	929	1,253	2,837	380	384	387	391	1,542	1,557	1,573	1,589	1,604	1,620
Facilities	266	364	362	160	161	163	165	649	656	662	669	676	682
Other	308	541	761	160	161	163	165	649	656	662	669	676	682
Options expense				500	600	600	600	2,300	2,760	3,312	3,974	4,769	5,723
Total Operating Expense	9,631	18,279	33,810	16,897	19,219	21,521	23,783	81,421	79,644	72,614	95,758	106,366	120,372
EBITDA													
Operating income	(9,631)	(18,279)	(33,810)	(16,897)	(19,219)	(21,521)	(23,783)	(81,421)	(79,644)	(72,614)	(11,329)	210,896	467,211
Interest (expense) income, net	-	1	8	21	8	21	8	58	8	58	8	58	8
Other income (expense), net	(1)	(3)	(9)	5	(9)	5	(9)	(8)	(9)	(8)	(9)	(8)	(9)
Pre-tax income (GAAP)	(9,632)	(18,281)	(33,811)	(16,871)	(19,220)	(21,495)	(23,784)	(81,371)	(79,645)	(72,564)	(11,330)	210,946	467,210
Pre-tax income (non-GAAP)													
Taxes (GAAP)		-	-	-	-	-	-	-	-	-	-	78,050	172,868
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)**	**(16,871)**	**(19,220)**	**(21,495)**	**(23,784)**	**(81,371)**	**(79,645)**	**(72,564)**	**(11,330)**	**132,896**	**294,342**
GAAP EPS (diluted)	($8.62)	($12.26)	($1.67)	($0.66)	($0.58)	($0.64)	($0.68)	($2.56)	($2.42)	($2.01)	($0.29)	$3.04	$6.12
Diluted shares	1,118	1,492											
Pro forma - diluted shares		9,514	21,574	25,656	33,000	33,495	34,828	31,745	32,856	36,142	39,756	43,731	48,104
Pro forma EPS (diluted)		**($1.92)**	**($1.67)**	**($0.66)**	**($0.58)**	**($0.64)**	**($0.68)**	**($2.56)**	**($2.42)**	**($2.01)**	**($0.29)**	**$3.04**	**$6.12**

Source: Company reports, Canaccord Genuity estimates

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Target Price / Valuation Methodology:

SAGE Therapeutics - SAGE

Our price target of $110 is based on a probability-adjusted P/S valuations.

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 06/10/15)

Rating	Coverage Universe		IB Clients
	#	%	%
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Hold	325	32.57%	15.38%
Sell	41	4.11%	7.32%
Speculative Buy	46	4.61%	56.52%
	998*	100.0%	

*Total includes stocks that are Under Review

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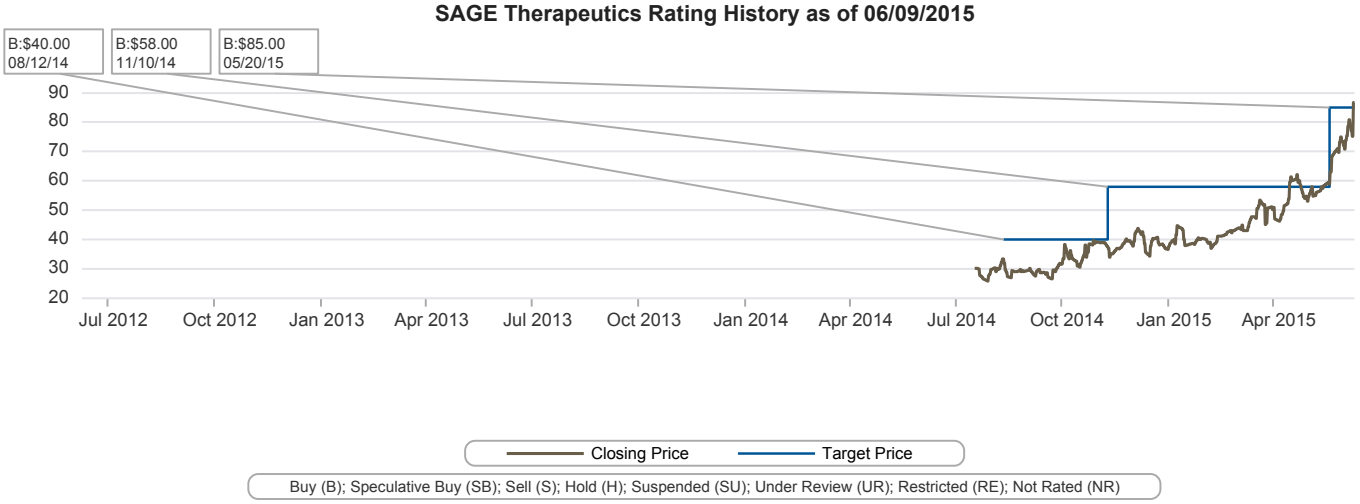
SAGE Therapeutics Rating History as of 06/09/2015



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