

Equity Research

June 9, 2015

Price: \$75.15 (06/8/2015)

Price Target: \$108.00 (Prior \$95.00)

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: SAGE
52-Week Range:	\$81.20 - 24.25
Market Cap (MM):	\$2,131.8
Net Debt (MM):	\$(127.8)
Cash/Share:	\$4.99
Dil. Shares Out (MM):	28.4
Enterprise Value (MM):	\$2,018.6
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$4.15
Dividend:	NA

FY (Dec)	2014E	2015E	2016E
Earnings Per Share			
Q1	-	(0.66)A	-
Q2	-	(0.73)	-
Q3	-	(0.79)	-
Q4	-	(0.84)	-
Year	(1.67)A	(3.02)	(3.34)
P/E	NM	NM	NM
Consensus EPS	-	(2.82)	(3.35)

Consensus source: Thomson Reuters

Revenue (MM)

Year	0.0	0.0	0.0
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Company Update

Positive Ph1/2 Exploratory PPD Results: Validates Mechanism in Large Unmet Need

The Cowen Insight

SAGE today announced positive top-line data in an exploratory Ph1/2 trial of '547 in Post-Partum Depression (PPD). We see this data as remarkably promising despite small numbers and open-label design. As a result, we add PPD to our valuation, increasing our PT from \$95 to \$108. We further think the data add credence to potential applications of SAGE's GABA compounds on neuropsychiatric conditions.

Ph1/2 '547 Exploratory Results on Post-Partum Depression (PPD) Promising: Consistent, Significant Reduction in Hamilton Depression Scale in 24hrs

SAGE announced topline data from its Ph1/2 exploratory trial of neuroactive steroid SAGE-547 (allopregnanolone) in 4 women with PPD and inadequate response to prior antidepressants. Adjunctive '547 therapy was associated with statistically significant improvement in the Hamilton Depression (HAM-D) scores within 24 hrs of treatment (p=0.001). At the end of the 60 hr treatment period, patients with mean baseline HAM scores of 26.5 improved to a mean score of 1.8. All 4 patients had consistent improvement in CGI-I scores. Notably, all patients began with severe HAM scores (>24), and all reduced to <7 (symptom-free). PPD is characterized by severely depressed moods and irritability within 4 weeks of giving birth and can manifest as late as 40 weeks postpartum. It is associated with low levels of allopregnanolone and affects up to 1M women in the US annually. 20% do not respond to current standard of care.

HAM-D Response Rate Compelling Despite Small Numbers, Open-Label Design. Benign Safety Consistent with Ph2 SRSE Experience

We note this single center study was originally designed to enroll 10-15 patients but was stopped early for overwhelming efficacy. SAGE indicated while the data is open-label, a 10-15% PBO 'responder' rate would have been expected. While PBO rates in neuro trials can range up to 30%: 1) Response is rarely symptom resolution and 2) The current trial showed a 100% resolution rate. '547 was safe and well tolerated, with only a small sedation signal. Additional patient followup is tbd, and there is no retreatment protocol currently. We expect full data to be published later this year, which should give more data detail.

Upcoming Ph2 PPD Trial: Our First Thoughts on Design

We look forward to SAGE starting of a PBO-controlled Ph2 study of '547 in PPD, likely in early 2016. While this trial, which we anticipate will have <100 pts, will use '547, we think final registrational trial maybe done with an optimized follow-on GABA-A compound. This trial served as proof of mechanism for Sage's GABA platform in non-seizure disorders. We note the '547 exploratory trial in essential tremor is still ongoing, and on track to produce first data in mid 2015.

At A Glance

Our Investment Thesis

We think Ph3 SAGE-547 could be a paradigm-changing new treatment option for super-refractory status epilepticus (SRSE), significantly decreasing the mortality and morbidity associated with the condition. Based on the strength of the Ph1/2 produced to date, we are optimistic for Ph3 success and think the drug could see widespread use in SRSE with ~\$1B peak sales. We think '547 success derisks the remainder of SAGE's GABA-based platform, at least for the indications related to seizure. '689 and '217 are in IND enabling studies as adjunctive treatments to RSE and orphan epilepsies, respectively.

Base Case Assumptions

- SAGE-547 is safe, effective, and superior to standard of care with efficacy similar to Ph1/2 data (~75% response rate)
- SAGE-689 and sage-217 are safe and well tolerated and generate solid clinical efficacy data

Upside Scenario

- SAGE-547 achieves higher than expected pricing and extremely high penetration rate, including potential earlier line use.
- SAGE-547 is effective in other indications
- Sage's follow-on compounds quickly generate impressive clinical data in multiple other indications

Forthcoming Catalysts

- SAGE-547 Exploratory Essential Tremor Data (2H15)
- SAGE-547 Ph3 Data (2H16)
- SAGE-689 IND (2H15)
- SAGE-217 IND (2H15)
- Sage announces additional follow-on compounds (2016)

Downside Scenario

- SAGE-547 fails the current Ph3 clinical trial
- SAGE-547 is not approved by the FDA and/or EMA
- SAGE-547 does not achieve expected pricing
- SAGE-547 does not achieve high levels of uptake

Price Performance



Source: Bloomberg

Company Description

Sage Therapeutics focuses on developing novel therapeutics for CNS-related indications with clear a unmet need. Lead compound SAGE-547 is in Ph3 for Super Refractory Status Epilepticus (SRSE), a disease that affects ~25K individuals/year in the US, and has high mortality and very poor current treatment options. Follow-on GABA-ergic compounds SAGE-689 and SAGE-217 are in development for Refractory Status Epilepticus (RSE) and orphan epilepsies, respectively. Sage also plans to develop an NMDA-receptor related compound.

Analyst Top Picks

	Ticker	Price (06/8/2015)	Price Target	Rating
Amicus Therapeutics	FOLD	\$13.06	\$19.00	Outperform
Cempra	CEMP	\$35.81	\$43.00	Outperform

We Model \$729MM Peak US Sales in PPD

We model \$729MM in peak US sales for PPD, with peak share at 33% in severe patients who do not respond well to available therapies. Based on assuming 2020 launch and 20% chance of success, the PPD indication adds ~\$14 to our pNPV.

SAGE Annual P&L

	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues										
SAGE-547 for SRSE	0.0	0.0	0.0	0.0	0.0	98.3	440.2	767.6	1,020.7	1,047.2
Total Revenues	0.0	0.0	0.0	0.0	0.0	98.3	440.2	767.6	1,020.7	1,047.2
Operating Expenses										
R&D	14.4	24.1	63.9	80.0	70.0	55.0	158.5	138.2	102.1	78.5
G&A	3.9	9.7	16.0	18.0	25.0	40.0	40.0	40.0	40.0	40.0
Total Operating Expenses	18.3	33.8	79.9	90.0	95.0	95.0	198.5	178.2	142.1	118.5
Loss from Operations	(18.3)	(33.8)	(79.9)	(90.0)	(95.0)	3.3	241.7	589.5	878.6	928.6
Interest income (expense)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
other income (expense)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net loss	(18.3)	(33.8)	(79.9)	(90.0)	(95.0)	3.3	241.7	589.5	878.6	928.6
Accretion of convertible preferred stock to redemption value	(0.0)	(2.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net loss attributable to common stockholders	(18.3)	(36.1)	(79.9)	(90.0)	(95.0)	3.3	241.7	589.5	878.6	928.6
EPS (basic and diluted)	\$ (12.26)	\$ (1.67)	\$ (3.02)	\$ (3.34)	\$ (3.45)	\$ 0.12	\$ 8.45	\$ 20.20	\$ 29.51	\$ 30.58
Number of shares (basic)	1.49	21.57	26.43	26.96	27.50	28.05	28.61	29.19	29.77	30.37
Number of shares (diluted)	1.49	21.57	26.43	26.96	27.50	28.05	28.61	29.19	29.77	30.37

Source: Cowen and Company

SAGE Quarterly P&L

	2013A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E
Revenues							
SAGE-547 for SRSE	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Expenses							
R&D	14.4	24.1	12.9	15.0	17.0	19.0	63.9
G&A	3.9	9.7	4.0	4.0	4.0	4.0	16.0
Total Operating Expenses	18.3	33.8	16.9	19.0	21.0	23.0	79.9
Loss from Operations	(18.3)	(33.8)	(16.9)	(19.0)	(21.0)	(23.0)	(79.9)
Interest income (expense)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
other income (expense)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0
Net loss	(18.3)	(33.8)	(16.9)	(19.0)	(21.0)	(23.0)	(79.9)
Accretion of convertible preferred stock to redemption value	(0.0)	(2.3)	0.0	0.0	0.0	0.0	0.0
Net loss attributable to common stockholders	(18.3)	(36.1)	(16.9)	(19.0)	(21.0)	(23.0)	(79.9)
EPS (basic and diluted)	\$ (12.26)	\$ (1.67)	\$ (0.66)	\$ (0.73)	\$ (0.79)	\$ (0.84)	\$ (3.02)
Number of shares (basic)	1.49	21.57	25.66	26.17	26.69	27.23	26.43
Number of shares (diluted)	1.49	21.57	25.66	26.17	26.69	27.23	26.43

Source: Cowen and Company

SAGE-547 Market Model

SAGE 547														
US SRSE		2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
SRSE														
# of SE cases (US)	1%	150,000	151,500	153,015	154,545	156,091	157,652	159,228	160,820	162,429	164,053	165,693	167,350	169,024
# of RSE cases (US)	30%	45,000	45,450	45,905	46,364	46,827	47,295	47,768	48,246	48,729	49,216	49,708	50,205	50,707
# of SRSE cases (US)	50%	22,500	22,725	22,952	23,182	23,414	23,648	23,884	24,123	24,364	24,608	24,854	25,103	25,354
patients amenable			70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Penetration			0%	10%	40%	60%	75%	75%	75%	75%	75%	75%	75%	75%
Patients on 547			0	1607	6491	9834	12415	12539	12665	12791	12919	13048	13179	13311
Price	2%	\$	60,000	\$ 61,200	\$ 62,424	\$ 63,672	\$ 64,946	\$ 66,245	\$ 67,570	\$ 68,921	\$ 70,300	\$ 71,706	\$ 73,140	\$ 74,602
SRSE 547 Revenues (MM)		\$	-	\$ 98.33	\$ 405.19	\$ 626.14	\$ 806.31	\$ 830.66	\$ 855.74	\$ 881.59	\$ 908.21	\$ 935.64	\$ 963.90	\$ 993.01
EU Top 5 SRSE														
# of SE cases (EU)	1%	75,000	75,750	76,508	77,273	78,045	78,826	79,614	80,410	81,214	82,026	82,847	83,675	84,512
# RSE cases (EU)	37%	27,750	28,028	28,308	28,591	28,877	29,166	29,457	29,752	30,049	30,350	30,653	30,960	31,269
# SRSE cases (EU)	50%	13,875	14,014	14,154	14,295	14,438	14,583	14,729	14,876	15,025	15,175	15,327	15,480	15,635
Patients amenable			70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Penetration			0%	0%	10%	40%	60%	60%	60%	60%	60%	60%	60%	60%
Patients on 547			0	0	1001	4043	6,125	6,186	6,248	6,310	6,373	6,437	6,502	6,567
Price		\$	45,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000	\$ 35,000
SRSE 547 EU Revenues (\$MM)		\$	-	\$ -	\$ 35.0	\$ 141.5	\$ 214.4	\$ 216.5	\$ 218.7	\$ 220.9	\$ 223.1	\$ 225.3	\$ 227.6	\$ 229.8
Total SRSE Revenues (\$MM)		\$	-	\$ 98.3	\$ 440.2	\$ 767.6	\$ 1,020.7	\$ 1,047.2	\$ 1,074.4	\$ 1,102.4	\$ 1,131.3	\$ 1,160.9	\$ 1,191.4	\$ 1,222.8
Postpartum Depression (US)														
# with Postpartum Depression (US)					1,000,000	1,020,000	1,040,400	1,061,208	1,082,432	1,104,081	1,126,162	1,148,686	1,171,659	
% severe, poor response	20%				200,000	204,000	208,080	212,242	216,486	220,816	225,232	229,737	234,332	
# needing new tx					800,000	816,000	832,320	848,966	865,946	883,265	900,930	918,949	937,328	
Penetration					5%	10%	20%	25%	30%	33%	33%	33%	33%	33%
PD pts on 547					10,000	20,400	41,616	53,060	64,946	72,869	74,327	75,813	77,330	
Price		\$	10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000
PD 547 Revenues (\$MM) (US)			\$	100	\$ 204	\$ 416	\$ 531	\$ 649	\$ 729	\$ 743	\$ 758	\$ 773	\$ 788	\$ 803

Source: Cowen and Company

SAGE pNPV

Assumptions / Results	
NPV (US\$)	108.34
Current price (US\$)	67.00
Upside (Downside)	62%
NoSH	25.7
Current market cap (US\$m)	
Implied market cap (US\$m)	
Pharma PE	15x
Discount rate	20%
Current year	2015.25

Drug name	Indication	Status	Estimated launch	Years to Launch	Years to Peak Sales	Success?	Peak Sales (US\$m)	Probability weighted Peak Sales (US\$m)	Royalty	Profitability	Probability weighted Peak Profit (US\$m)	Discount Factor	NPV (US\$)
SAGE-547	SRSE (US)	Phase 3	2018	2.8	7.8	65%	856	556	96%	100%	533.98	4.11	78.48
	SRSE (EU)	Phase 3	2019	3.8	8.8	60%	221	133	96%	100%	127.22	4.93	15.58
follow-on	PPD	Ph1/2	2020	4.8	9.8	20%	729	146	96%	100%	139.91	5.92	14.28
Total													108.34

Source: Cowen and Company

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

SAGE's lead program has been successful in a Ph1/2 trial. This, however, does not guarantee success in future trials as well as success in trials for SAGE's follow-on compounds, '217 and '689. Clinical success does also not guarantee commercial success, and while we believe '547 can achieve \$75K pricing and a 75% market share in the US, these are our projections and SAGE may not reach these sales figures.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
FOLD	Amicus Therapeutics
CEMP	Cempra
SAGE	Sage Therapeutics

Analyst Certification

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Sage Therapeutics, Cempra and Amicus Therapeutics have been client(s) of Cowen and Company, LLC in the past 12 months.

Cowen and Company, LLC and/or its affiliates expect to receive, or intend to seek, compensation for investment banking services in the next 3 months from Sage Therapeutics.

Sage Therapeutics, Cempra and Amicus Therapeutics is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Sage Therapeutics, Cempra and Amicus Therapeutics.

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

Cowen And Company Rating Definitions

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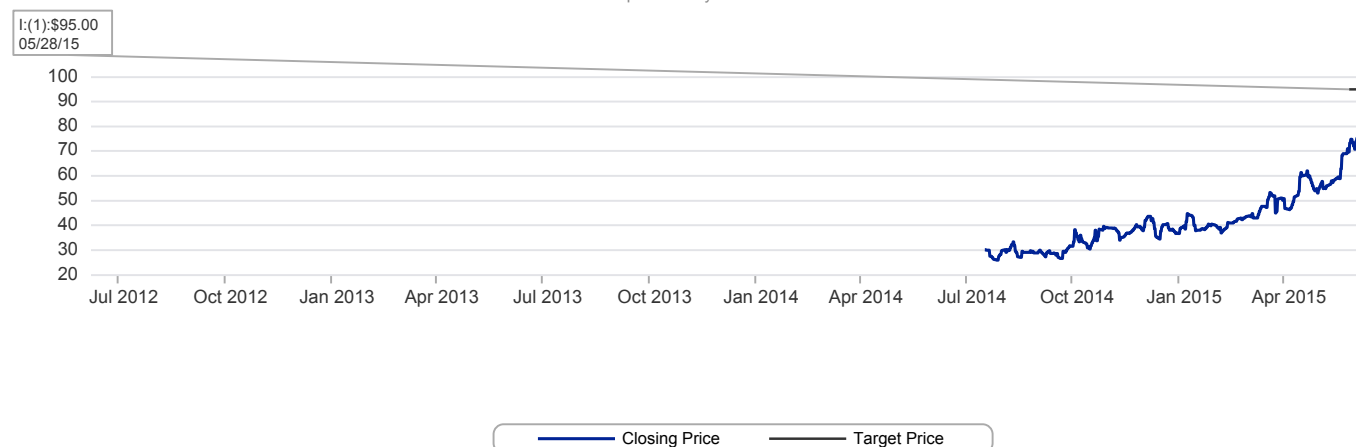
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	450	58.67%	103	22.89%
Hold (b)	302	39.37%	8	2.65%
Sell (c)	15	1.96%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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Sage Therapeutics Rating History as of 06/08/2015

powered by: BlueMatrix



Cempra Rating History as of 06/08/2015

powered by: BlueMatrix



Amicus Therapeutics Rating History as of 06/08/2015

powered by: BlueMatrix



Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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