

Sage Therapeutics

Notes from the Road

We're reiterating our OW rating on SAGE after hosting CEO Jeffrey Jonas, CFO Kimi Iguchi, and Chief Commercial Strategy Officer Thomas Anderson for investor meetings on Tuesday. The updates were largely incremental following the company's July IPO and our recent initiation ([here](#)). Most notably, management believes that it is on track (or ahead of schedule) with the Phase 1/2 trial and remains confident they will be reporting top-line data before year-end. The company also reiterated timelines for INDs for 689 (by year-end) and 217 (by mid-2015) and indicated that we could hear about a new molecule from the NMDA program next year. More detailed takeaways are outlined below. Overall, we see Sage as well positioned with a near-term catalyst as well as likely additional data updates and regulatory progress throughout 2015 that could continue to de-risk the story and drive upside.

- **Top-line data from Phase 1/2 trial evaluating SAGE-547 in SRSE will read out before year-end, with a more detailed data presentation to come at a medical meeting.** Management is "extremely comfortable" in its initial guidance for a data readout (with 10-15 pts enrolled) by year-end. They also noted that top-line results would be made public via a press release, followed by a more granular data presentation at a medical meeting, potentially the American Epilepsy Society meeting (Dec. 5-9, Seattle). On enrollment, the company isn't providing updates on patient numbers, but noted that 16 sites are now open (vs. 10 at the time of our August initiation) and that accrual is going well overall. Management also noted that centers across the US see an average of 1-4 pts per year, but that number can be highly variable from center to center (ranging from 0-200 patients) in a given year and also can be seasonal.
- **Pivotal SAGE-547 trial on track to start mid-2015, and management is still guiding for 1-2 years until data.** This guidance is unchanged from prior expectations. Given the company has yet to meet with the FDA (will do an EOP2), there aren't any updates regarding trial design and patient numbers. Specifically on endpoints, management noted that they may end up switching around the endpoints in the pivotal vs. the Phase 1/2 trial as the FDA may find the current secondary endpoint (ability to remain SE free w/o 547 on board) to be more clinically relevant (vs. the current primary endpoint of resolution of SE with 547 on board post wean). Importantly, those two endpoints have correlated with each other to date. This is something we expect investors to pay close attention to when Phase 1/2 data are released.

Sage Therapeutics, Inc. (SAGE;SAGE US)

FYE Dec	2012A	2013A	2014E	2015E
EPS reported (\$)				
Q1 (Mar)	-	(0.76)	(1.17)A	-
Q2 (Jun)	-	-	(4.57)A	-
Q3 (Sep)	-	-	(0.61)	-
Q4 (Dec)	-	-	(0.45)	-
FY	(2.74)	(2.15)	(2.93)	(2.26)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Overweight

SAGE, SAGE US

Price: \$31.26

Price Target: \$42.00

Biotechnology

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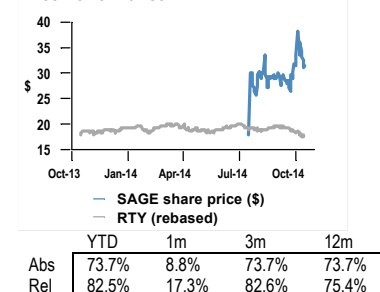
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Price Performance



Company Data

Price (\$)	31.26
Date Of Price	15 Oct 14
52-week Range (\$)	40.74-24.25
Market Cap (\$ mn)	53.16
Fiscal Year End	Dec
Shares O/S (mn)	2
Price Target (\$)	42.00
Price Target End Date	31-Dec-15

See page 5 for analyst certification and important disclosures.

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- **Patient differences between emergency use and the Phase 1/2 trial patients could lead to differential longer-term outcomes.** SAGE noted that patients in the Phase 1/2 trial are acutely ill with the underlying etiology at the time of treatment, which is different from the eIND patients whose other conditions were largely stabilized by the time 547 was tried. SAGE reiterated that 547 isn't treating the underlying etiology (e.g. viral infection, blood on the brain post head trauma), thus SE could recur once 547 is tapered (or sometime in the 30-day follow-up period). This generally wasn't the case in the eIND patients who had been in medically induced comas for at least 30+ days, such that their underlying issue was largely resolved and the primary issue was the SE. Importantly, SAGE believes the potential for SE to recur in these acutely ill patients isn't a regulatory issue, but potentially a commercial one as it could affect how 547 is used.
- **SAGE continues to execute on the pipeline; recent 217 data highlights the improved clinical profile of 2nd-gen compounds.** SAGE reviewed the recently presented preclinical data on 217, showing the drug is more potent at $\alpha 1$ and $\alpha 4$, with less off-target effects. Given this compound can be dosed orally (likely QD), the company will likely take this drug forward first in an orphan genetic epilepsy indication (e.g. Fragile X, Dravet), with the potential for maintenance dosing in SE as another indication. An IND is expected by mid-2015. Progress with 689 (also more potent vs. 547 and also an IV) is still proceeding on schedule, with an IND expected by year-end. The future of this compound is less clear, as company noted that depending on how the data shapes up, it has the potential to cannibalize 547.
- **NMDA program could produce a drug candidate next year, likely in an orphan, monogenic disease driven by a mutation in NMDA receptor.** While the company continues to focus mostly on the GABA programs, some incremental work is being done in the NMDA arena. Mgmt indicated that they will try to replicate what they have done in the GABA program, i.e. look for small, orphan indications where NMDA is the known problem and there are no current treatments. The company believes they have found at least one potential indication and could announce a lead molecule next year.

Investment Thesis, Valuation and Risks

Sage Therapeutics (Overweight; Price Target: \$42.00)

Investment Thesis

We have an OW rating on SAGE based on the potential of SAGE-547 for the treatment of super-refractory status epilepticus (SRSE) – a life-threatening state of persistent seizure that is unresponsive to currently available therapies (and an orphan indication). We believe SAGE-547's unique mechanism of action should continue to generate positive data and that the significant unmet need in SRSE will drive uptake of SAGE-547 upon commercialization. Follow-on candidates SAGE-689 and SAGE-217 for earlier lines of SE could grow the top line with significant infrastructure synergy.

Valuation

Our probability-weighted Dec-15 PT of \$42 is based on a blended average of our proprietary probability-adjusted sum-of-the-parts scenario analysis (50% weighting) and risk-adjusted NPV model (50% weighting).

SAGE Valuation Summary

SAGE Valuation Summary			
Discount rate	14%		
4Q15 Fully Diluted Shares (m)	29.0		
Main value drivers	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr
SAGE-547- Status Epilepticus - US	60%	\$ 1,032	2022
SAGE-547- Status Epilepticus - G7	50%	\$ 582	2024
Valuation methodology	Value / share	Weighting	Adj. value/ share
DCF			
P/E 2016			
Real options scenario analysis	\$ 42.32	50%	21.16
Risk adjusted NPV analysis	\$ 42.05	50%	21.03
Total			\$ 42.19
Catalyst/liquidity discount			0%
YE15 Price Target			\$ 42

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

SAGE is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. More specific risks to the downside include clinical setbacks for the key pipeline product SAGE-547 and pre-clinical candidates SAGE-689 and SAGE-217, regulatory hurdles, commercial setbacks and personnel risk.

Sage Therapeutics: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14A	3Q14E	4Q14E
Revenues	0	0	0	-	Revenues	0A	0A	0	0
Cost of products sold	0	0	0	-	Cost of products sold	0A	0A	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(4)	(8)	(14)	-	SG&A	(2)A	(2)A	(2)	(2)
R&D	(14)	(25)	(48)	-	R&D	(4)A	(4)A	(7)	(10)
Operating income	(18)	(32)	(62)	-	Operating income	(6)A	(6)A	(8)	(12)
EBITDA	(18)	(32)	(62)	-	EBITDA	(6)A	(6)A	(8)	(12)
Net interest (income) / expense	-	-	-	-	Net interest (income) / expense	-	-	-	-
Other income / (expense)	(0)	(0)	0	-	Other income / (expense)	0A	(0)A	0	0
Income taxes	0	0	0	-	Income taxes	0A	0A	0	0
Net income - GAAP	(18)	(34)	(62)	-	Net income - GAAP	(6)A	(8)A	(8)	(12)
Net income - recurring	(18)	(34)	(62)	-	Net income - recurring	(6)A	(8)A	(8)	(12)
Diluted shares outstanding	8	12	27	-	Diluted shares outstanding	5A	2A	14	26
EPS - excluding non-recurring	(2.15)	(2.93)	(2.26)	-	EPS - excluding non-recurring	(1.17)A	(4.57)A	(0.61)	(0.45)
EPS - recurring	(2.15)	(2.93)	(2.26)	-	EPS - recurring	(1.17)A	(4.57)A	(0.61)	(0.45)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	8	122	181	-	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	89.8%	75.5%	94.1%	-
Inventories	-	-	-	-	EPS growth - recurring	(21.3%)	36.0%	(22.6%)	-
Other current assets	0	0	0	-					
Current assets	8	123	182	-	Gross margin	-	-	-	-
PP&E	0	0	0	-	EBIT margin	-	-	-	-
Total assets	9	123	182	-	EBITDA margin	-	-	-	-
				-	Tax rate	0.0%	0.0%	0.0%	-
Total debt	0	0	0	-	Net margin	-	-	-	-
Total liabilities	2	3	3	-					
Shareholders' equity	6	120	179	-	Net Debt / EBITDA	42.3%	379.7%	290.4%	-
				-	Net Debt / Capital (book)	494.2%	6916.1%	9352.3%	-
Net income (including charges)	(18)	(34)	(62)	-					
D&A	0	0	0	-	Return on assets (ROA)	(317.3%)	(51.8%)	(40.9%)	-
Change in working capital	1	0	0	-	Return on equity (ROE)	(472.0%)	(53.9%)	(41.7%)	-
Other	0	1	1	-					
Cash flow from operations	(18)	(33)	(61)	-	Enterprise value / sales	-	-	-	-
				-	Enterprise value / EBITDA	NM	2.2	2.1	-
Capex	(0)	0	0	-	Free cash flow yield	(6.6%)	(9.1%)	(7.1%)	-
Free cash flow	(18)	(33)	(61)	-					
Cash flow from investing activities	(0)	0	0	-					
Cash flow from financing activities	23	147	120	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

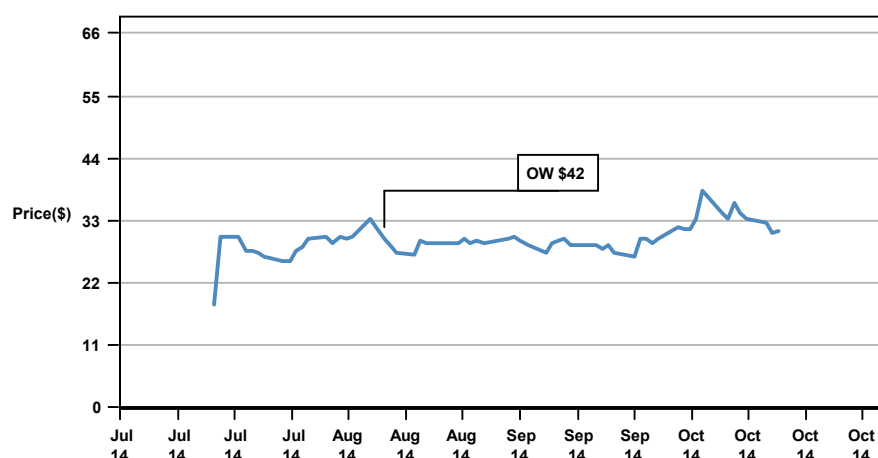
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Sage Therapeutics (SAGE, SAGE US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
12-Aug-14	OW	31.81	42.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Aug 12, 2014.

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