Sage Therapeutics

SAGE 547 Continues to Demonstrate Promising Efficacy in SRSE

Overweight

SAGE, SAGE US
Price: $44.73

▲ **Price Target: $51.00**
Previous: $42.00

We are reiterating our OW rating and raising our Dec-15 target on SAGE after this morning's announcement of updated Phase 1/2 data for SAGE-547 in SRSE. To date, 20 patients have been enrolled (vs. 12 as of the update in early Nov.). Of the 17 evaluable for efficacy, 12 (71%) met the primary endpoint, in line with the 73% (8 of 11) patients as of the last update. We got a chance to speak with management who highlighted the drug has shown efficacy in pts with a range of underlying etiologies, and the updated 78% response rate in eIND patients further supports the consistency of the data. The drug continued to be well tolerated; 5 deaths during the study period were not considered to be drug related (and are not surprising given the severity of the underlying disease in these patients). Bottom line, today's update provides a more robust data set that confirms the early efficacy profile. We continue to see Sage as well positioned, with focus likely now turning to regulatory progress as well as further data updates in 2015 that could continue to de-risk the story.

- **SAGE-547 demonstrates continued safety and efficacy in 8 additional Phase 1/2 pts enrolled since Nov.** In 17 pts evaluable for efficacy, all 71% of who met the primary endpoint (successful wean from anesthetics with SAGE-547 on board) were also weaned off SAGE-547 without recurrence of SRSE. In the eIND setting 10 pts have been treated (up from 7 prvsly), and 7 of 9 patients (78%) had resolution of SRSE during or soon after 547 treatment (10th patient outcome is pending).

- **We are encouraged by the consistency of the data in both acutely ill and more stable patients with a range of underlying etiologies.** The Phase 1/2 trial enrolled more acutely ill pts with the mean duration of SRSE prior to 547 treatment of 11 days. In these pts the cause of SRSE was attributed to hemorrhage (n=4), infections (n=4), worsening of seizures (n=2), primary or metastatic brain tumors (n=2), stroke, sickle cell anemia, Lupus, PRES and toxic ingestion (all n=1) and unknown (n=3). The 10 eIND pts tended to be more stabilized, having been in SRSE for ~30+ days prior to 547 treatment, with a similar range of underlying etiologies.

- **Responders had rapid improvement in disease state and acute brain injury, with continued improvement during the 30 day follow up period.** Patients were assessed at baseline and throughout the trial using the Clinical Global Impression of Severity (CGI-S) scale and the Glasgow Coma Scale (which assesses the severity of an acute brain injury). By day 30, responders demonstrated a 3-step improvement in their illness per the CGI-S (to "mildly ill" from "most extremely ill"/"severely ill") while non-responders did not improve from "severely ill."

Biotechnology

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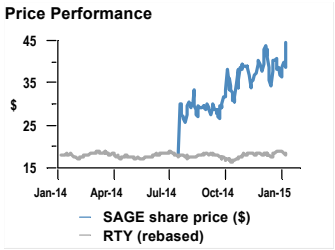

	YTD	1m	3m	12m
Abs	15.6%	7.2%	23.9%	148.5 %
Rel	15.8%	4.7%	14.9%	145.2 %

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)	-	-	(0.50)A	-
Q4 (Dec)	-	-	(0.44)	-
FY	(2.74)	(2.15)	(2.69)	(2.26)

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

Company Data	
Price ($)	44.73
Date Of Price	08 Jan 15
52-week Range ($)	44.98-24.25
Market Cap ($ mn)	1,153.72
Fiscal Year End	Dec
Shares O/S (mn)	26
Price Target ($)	51.00
Price Target End Date	31-Dec-15

See page 5 for analyst certification and important disclosures.

- **Next steps… an End-of-Phase-2 meeting with the FDA, and clarity on the path to registration.** SAGE noted that the EoPh2 meeting is scheduled, and we expect clarity on the regulatory path in 1H15, which could be a significant driver for shares. While SAGE maintains that it will run a pivotal trial, we think there remains the possibility for an accelerated path given 1) the efficacy to date and 2) the degree of unmet need in SRSE. We also expect the company will apply for Breakthrough Therapy Designation, which if granted, may also facilitate an accelerated path to market.
- **We are increasing our Dec-15 target to $51 from $42 on increased confidence in the ultimate potential of SAGE-547.** We lowered the discount rate to 12% from 13.5% based 1) on the company's WACC and 2) on our increased confidence in the longer term outlook for SAGE 547. We have also skewed the probabilities assigned to various commercial scenarios slightly more aggressively. We estimate peak US sales of SAGE-547 in SRSE of ~$1B. Of the ~150,000 cases/year of SE in the US, Sage estimates ~25K ultimately progress to SRSE. SAGE-547 has been granted fast-track designation from the FDA, and we assume NDA approval and launch in 2H17. We (perhaps conservatively) assume a launch price of $50K per administration, with SAGE-547 reaching peak share of 75% in 2022. Based on doc feedback, we also assume some off-label use in RSE, where it reaches peak penetration of 25% in 2022. See our initiation (here) for more details on our market and revenue assumptions.

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Investment Thesis, Valuation and Risks

Sage Therapeutics *(Overweight; Price Target: $51.00)*

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 $51 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	12%		
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	$ 55.45	50%	27.73
Risk adjusted NPV analysis	$ 47.24	50%	23.62
Total			$ 51.35
Catalyst/liquidity discount			0%
YE15 Price Target			**$ 51**

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.

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J.P.Morgan

Sage Therapeutics: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E
Revenues	0	0	0	-
Cost of products sold	0	0	0	-
Gross profit	-	-	-	-
SG&A	(4)	(9)	(14)	-
R&D	(14)	(23)	(48)	-
Operating income	(18)	(33)	(62)	-
EBITDA	(18)	(33)	(62)	-
Net interest (income) / expense	-	-	-	-
Other income / (expense)	(0)	(0)	0	-
Income taxes	0	0	0	-
Net income - GAAP	(18)	(35)	(62)	-
Net income - recurring	(18)	(35)	(62)	-
Diluted shares outstanding	8	13	27	-
EPS - excluding non-recurring	(2.15)	(2.69)	(2.26)	-
EPS - recurring	(2.15)	(2.69)	(2.26)	-

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	8	121	180	-
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	0	0	0	-
Current assets	8	121	180	-
PP&E	0	0	0	-
Total assets	9	121	180	-
Total debt	0	0	0	-
Total liabilities	2	3	3	-
Shareholders' equity	6	119	178	-
Net income (including charges)	(18)	(35)	(62)	-
D&A	0	0	0	-
Change in working capital	1	0	0	-
Other	0	1	1	-
Cash flow from operations	(18)	(34)	(61)	-
Capex	(0)	0	0	-
Free cash flow	(18)	(34)	(61)	-
Cash flow from investing activities	(0)	0	0	-
Cash flow from financing activities	23	147	120	-
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q14A	2Q14A	3Q14A	4Q14E
Revenues	0A	0A	0A	0
Cost of products sold	0A	0A	0A	0
Gross profit	-	-	-	-
SG&A	(2)A	(2)A	(3)A	(3)
R&D	(4)A	(4)A	(7)A	(8)
Operating income	(6)A	(6)A	(9)A	(11)
EBITDA	(6)A	(6)A	(9)A	(11)
Net interest (income) / expense	-	-	-	-
Other income / (expense)	0A	(0)A	0A	0
Income taxes	0A	0A	0A	0
Net income - GAAP	(6)A	(8)A	(10)A	(11)
Net income - recurring	(6)A	(8)A	(10)A	(11)
Diluted shares outstanding	5A	2A	20A	26
EPS - excluding non-recurring	(1.17)A	(4.57)A	(0.50)A	(0.44)
EPS - recurring	(1.17)A	(4.57)A	(0.50)A	(0.44)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	-	-	-	-
EBIT growth	89.8%	79.7%	89.5%	-
EPS growth - recurring	(21.3%)	24.8%	(15.7%)	-
Gross margin	-	-	-	-
EBIT margin	-	-	-	-
EBITDA margin	-	-	-	-
Tax rate	0.0%	0.0%	0.0%	-
Net margin	-	-	-	-
Net Debt / EBITDA	42.3%	367.3%	288.5%	-
Net Debt / Capital (book)	494.2%	6850.2%	9292.3%	-
Return on assets (ROA)	(317.3%)	(54.1%)	(41.2%)	-
Return on equity (ROE)	(472.0%)	(56.2%)	(42.0%)	-
Enterprise value / sales	-	-	-	-
Enterprise value / EBITDA	NM	NM	NM	-
Free cash flow yield	(4.6%)	(5.8%)	(5.0%)	-

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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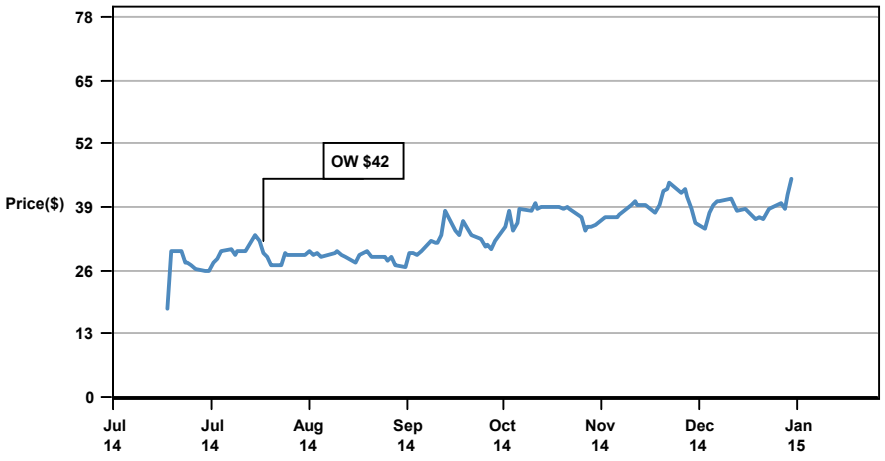
Sage Therapeutics (SAGE, SAGE US) Price Chart



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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