

Sage Therapeutics

Follow-Up Thoughts Post Conversation with Management; Increasing PT on Slightly Higher Probability of Success

Following this morning's announcement of the pivotal path for SAGE-547 in SRSE (see our note [here](#)), we are updating our model to reflect an increased probability of success for SAGE-547 in the US and EU (we now assume a 70% POS in the US, 60% in the EU). We also got a chance to speak with mgmt; they were not surprisingly pleased with their FDA interactions and confident in the outlook for the drug. The company believes the Phase 3 trial design is the fastest way to get this drug approved with the broadest label. Sage reiterated its expectation for 1-2 years from trial start to data (hopeful it can be on the shorter end of the range), and noted there has been a significant amount of incoming interest from potential sites both in the US and EU.

- **Phase 3 trial designed to give the broadest label possible and fastest path to market.** The 1:1 randomization provides for the most efficient statistical design/provides the fastest answer (and placebo non-responders can cross-over and receive the higher 547 dose). On powering, SAGE refrained from providing specifics but noted the response rate assumption for the SAGE-547 arm is conservative relative to the ~70% seen in the Phase 1/2 trial, and the assumption in the placebo arm is ~35% (based on historical data, also very conservative in our view). On the higher dose, the company noted an additional 5-10 patients had been enrolled in the Phase 1/2 trial at that dose and it (and the FDA) was comfortable with the data there so far (results at this dose have not yet been publicly presented). On the other hand, SAGE doesn't anticipate the higher dose will be used that often given the response rate seen at the 1st dose.
- **BTD may be an option at some point, but the focus is on getting the pivotal program underway.** SAGE noted that BTD requires some controlled or historical data, and given the relative lack of historical data in this disease, it believes it will qualify for the designation at some point when some controlled data has been generated. That said, it noted that it has progressed very rapidly through regulatory discussion with the agency without the designation.
- **Official talks with the EMA are planned and EU partnership interest is increasing, though SAGE focused on maintaining the value of the asset.** While there are a few subtle differences between US and EU practices, SAGE noted the key variables (weaning process and 3L agents used) were largely the same in the US and EU. On the BD front, the company noted an uptick in incoming interest from potential partners, though reiterated they have the resources/know how to take the program forward on its own.

Sage Therapeutics, Inc. (SAGE;SAGE US)

FYE Dec	2012A	2013A	2014A	2015E
EPS reported (\$)				
Q1 (Mar)	-	(0.76)	(1.17)	(0.49)
Q2 (Jun)	-	-	(4.57)	(0.55)
Q3 (Sep)	-	-	(0.50)	(0.64)
Q4 (Dec)	-	-	(0.48)	(0.78)
FY	(2.74)	(2.15)	(1.67)	(2.48)

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

Overweight

SAGE, SAGE US

Price: \$50.86

▲ **Price Target: \$58.00**
Previous: \$51.00

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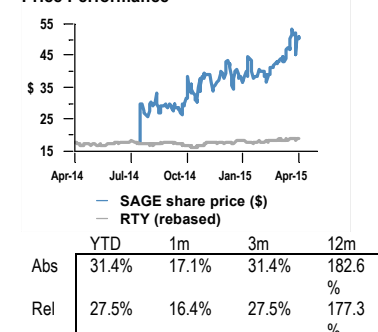
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Price Performance



Company Data

Price (\$)	50.86
Date Of Price	01 Apr 15
52-week Range (\$)	55.01-24.25
Market Cap (\$ mn)	1,312.65
Fiscal Year End	Dec
Shares O/S (mn)	26
Price Target (\$)	58.00
Price Target End Date	31-Dec-15

See page 5 for analyst certification and important disclosures.

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- **We are increasing our Dec-15 target to \$58 from \$51 on increased confidence in the ultimate potential of SAGE-547.** We have increased the probability of success we assign to SAGE-547 WW by 10% (to 70% in the US and 60% in the EU). We estimate peak US sales of SAGE-547 in SRSE of ~\$1B. Of the ~150,000 cases/year of SE in the US, we estimate ~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.

Investment Thesis, Valuation and Risks

Sage Therapeutics (Overweight; Price Target: \$58.00)

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 \$58 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	70%	\$ 1,032	2022
SAGE-547- Status Epilepticus - G7	60%	\$ 582	2024
Valuation methodology	Value / share	Weighting	Adj. value/ share
DCF			
P/E 2016			
Real options scenario analysis	\$ 64.14	50%	32.07
Risk adjusted NPV analysis	\$ 52.25	50%	26.12
Total			\$ 58.19
Catalyst/liquidity discount			0%
YE15 Price Target			\$ 58

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	FY14A	FY15E	FY16E	FY17E	Income Statement - Quarterly	1Q15E	2Q15E	3Q15E	4Q15E
Revenues	0	0	-	-	Revenues	0	0	0	0
Cost of products sold	0	0	-	-	Cost of products sold	0	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(10)	(15)	-	-	SG&A	(4)	(4)	(4)	(4)
R&D	(24)	(53)	-	-	R&D	(9)	(11)	(14)	(19)
Operating income	(34)	(68)	-	-	Operating income	(13)	(14)	(18)	(23)
EBITDA	(34)	(68)	-	-	EBITDA	(13)	(14)	(18)	(23)
Net interest (income) / expense	-	-	-	-	Net interest (income) / expense	-	-	-	-
Other income / (expense)	(0)	0	-	-	Other income / (expense)	0	0	0	0
Income taxes	0	0	-	-	Income taxes	0	0	0	0
Net income - GAAP	(36)	(68)	-	-	Net income - GAAP	(13)	(14)	(18)	(23)
Net income - recurring	(36)	(68)	-	-	Net income - recurring	(13)	(14)	(18)	(23)
Diluted shares outstanding	22	27	41	-	Diluted shares outstanding	26	26	28	30
EPS - excluding non-recurring	(1.67)	(2.48)	-	-	EPS - excluding non-recurring	(0.49)	(0.55)	(0.64)	(0.78)
EPS - recurring	(1.67)	(2.48)	-	-	EPS - recurring	(0.49)	(0.55)	(0.64)	(0.78)
Balance Sheet and Cash Flow Data	FY14A	FY15E	FY16E	FY17E	Ratio Analysis	FY14A	FY15E	FY16E	FY17E
Cash and cash equivalents	120	173	-	-	Sales growth	-	-	-	-
Accounts receivable	-	-	-	-	EBIT growth	84.9%	101.4%	-	-
Inventories	-	-	-	-	EPS growth - recurring	(22.3%)	48.1%	-	-
Other current assets	0	0	-	-	Gross margin	-	-	-	-
Current assets	120	174	-	-	EBIT margin	-	-	-	-
PP&E	0	0	-	-	EBITDA margin	-	-	-	-
Total assets	120	174	-	-	Tax rate	0.0%	0.0%	-	-
Total debt	0	0	-	-	Net margin	-	-	-	-
Total liabilities	3	3	-	-	Net Debt / EBITDA	354.1%	253.8%	-	-
Shareholders' equity	118	171	-	-	Net Debt / Capital (book)	6796.2%	8941.1%	-	-
Net income (including charges)	(36)	(68)	-	-	Return on assets (ROA)	(56.0%)	(46.3%)	-	-
D&A	0	0	-	-	Return on equity (ROE)	(58.2%)	(47.2%)	-	-
Change in working capital	0	0	-	-	Enterprise value / sales	-	-	-	-
Other	1	1	-	-	Enterprise value / EBITDA	NM	NM	-	-
Cash flow from operations	(35)	(67)	-	-	Free cash flow yield	(3.2%)	(4.8%)	-	-
Capex	0	0	-	-					
Free cash flow	(35)	(67)	-	-					
Cash flow from investing activities	0	0	-	-					
Cash flow from financing activities	147	120	-	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

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

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

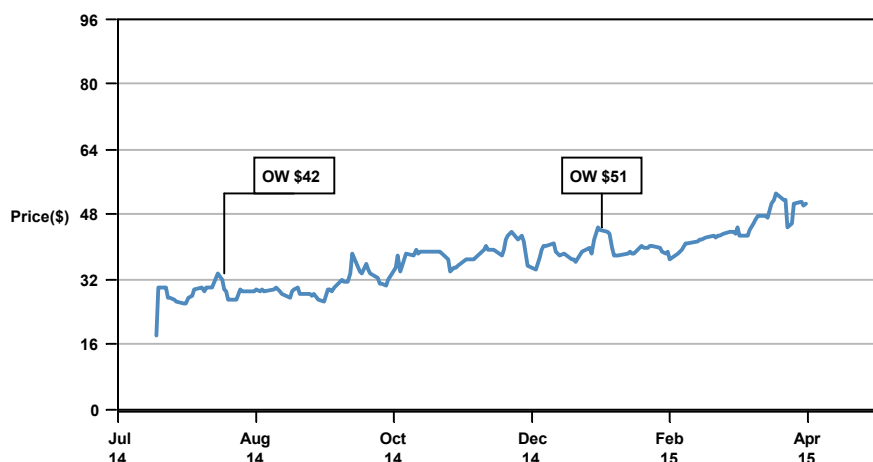
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Sage Therapeutics (SAGE, SAGE US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
12-Aug-14	OW	33.40	42.00
09-Jan-15	OW	44.73	51.00

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

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