Sage Therapeutics

Upside Surprise - Positive Initial PPD Data Show Strong, Consistent Response - ALERT

Overweight

SAGE, SAGE US
Price: $75.15

08 June 2015

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We are reiterating our OW rating on SAGE after the company announced positive early data for SAGE-547 in post-partum depression (PPD). The exploratory open label trial (n=4) demonstrated a stat sig (paired t-test p=0.001) improvement from baseline in Hamilton Rating Scale for Depression (HAM-D) within 24h after IV administration of SAGE-547. The trial was subsequently stopped early given consistency/strength of the signal, and now the company intends to move forward into randomized testing with 547. At the same time, SAGE will also advance novel molecules that could ultimately be used in this indication. We are encouraged by these data (albeit uncontrolled, single center, and in only 4 patients) and note that this opportunity is not currently included in our model (SAGE notes that ~20% of women are affected with PPD after childbirth). Overall, we continue to see SAGE as well positioned with SAGE-547 in SRSE progressing on schedule (Phase 3 to start mid-2015), this positive PPD data in an indication not yet in included in our model, plus an additional data read-out (547 in essential tremor) also expected in mid-2015.

- **Trial design.** The Phase 2 trial (here) initially intended to enroll 15 patients, but was stopped early given the consistency and magnitude of response. Enrolled patients all experienced a major depressive episode (per the Structured Clinical Interview for DSM-IV Axis I Disorders) within the first 4 weeks after delivery. Patients were treated as in-patients, and had inadequate responses to prior antidepressant therapy. SAGE-547 was administered in a proprietary dosing schedule as an adjunctive therapy. .

- **Treatment with SAGE-547 resulted in a significant treatment effect, with patients improving from a mean 26.5 HAM-D score at baseline to 1.8 after 60h treatment period.** All 4 pts treated rapidly achieved remission (a HAM-D score less than 7 is considered symptom free, greater than 24 is severe), and patients also demonstrated consistent improvements in the Clinical Global Impression-Improvement (CGI-I) scale. SAGE-547 was well tolerated, with no SAEs observed during the 60h treatment period or the 30 day follow up. In total, 14 AEs were reported, with sedation being the only one observed in more than one patient.

- **Next steps… SAGE will move into a placebo controlled trial "as rapidly as possible."** We expect a randomized trial would enroll a similar patient population, though anticipate a longer trial (likely 4-6 weeks vs. the 60 hour treatment period in the current trial).

- **PPD represents a potentially large market, though we note the majority of patients can be successfully managed with current therapies.** The American Psychological Association estimates that 9%-16% of women who give birth will experience PPD. That rate increases to 41% for women who have already experienced PPD with a prior pregnancy. With almost 4 million babies born in the US in 2013, PPD could present a large revenue opportunity. We do caveat, however, the majority (up to 90% depending on the source) of patients can be successfully treated with medication or a combination of medication and psychotherapy.

See page 2 for analyst certification and important disclosures.

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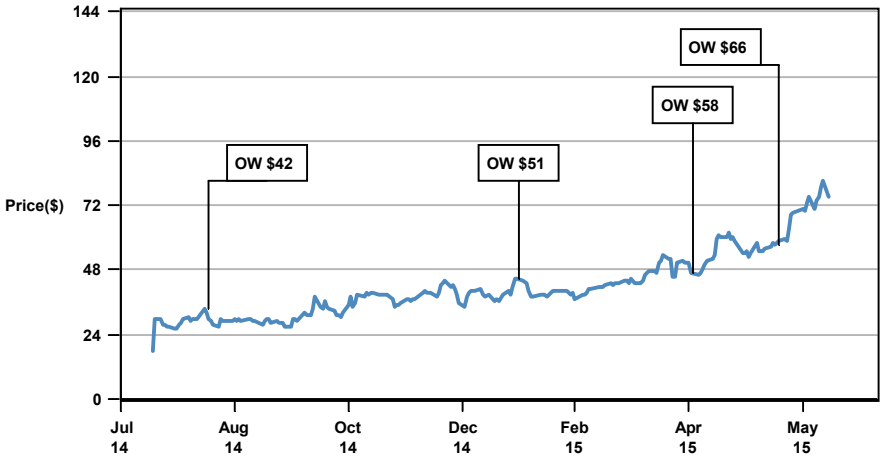
Sage Therapeutics (SAGE, SAGE US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
12-Aug-14	OW	33.40	42.00
09-Jan-15	OW	44.73	51.00
02-Apr-15	OW	46.87	58.00
14-May-15	OW	57.29	66.00

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

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