CANACCORD Genuity

SAGE Therapeutics

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Biotechnology

US Equity Research

14 May 2015

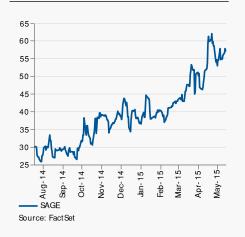
BUY

 PRICE TARGET
 US\$58.00

 Price (14-May)
 US\$57.54

 Ticker
 SAGE-NASDAQ

52-Week Range (US\$): 24.25 - 63.77
Avg Daily Vol (000s): 272.20
Shares Out. (M): 28.1
Market Cap (US\$M): 1,616.5



SAGE Therapeutics is a biopharmaceutical company focused on developing drugs to treat CNS disorders where no effective options exist.

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Final phase 1/2 547 data consistent; await ET/ PPD data mid-2015; phase 3 allows higher dose retreatment

Final Phase 1/2 data for 547 consistent, 77% success, no recurrence within 24 hours

SAGE-547 continued to demonstrate a robust 77% response rate in n=22 evaluable patients (25 total), in which these patients were able to be weaned off the study drug without recurrence of SRSE within 24 hours, a positive. Out of the total responders, 4 patients relapsed (one at week 1-2, others at weeks 2-4), which is typical for these type of populations given their acute state. Six patients deaths were recorded, with the majority (n=4) being non-responders. We remind investors that these patients failed a prior weaning attempt and had no other viable therapeutic options.

Exploratory essential tremor, post-partum depression data mid-year for 547

We expect SAGE-547 exploratory data in essential tremors and post-partum depression by mid-2015, which could suggest activity for indications outside of super refractory status epilepticus (SRSE). The essential tremor (ET) study is double-blind, placebo-controlled, and ascending dose, whereas the post-partum depression (PPD) study is open label. Although these studies are mainly PK and safety trials, we still expect outcome measures (tremors by accelerometer and depression by HAM-D-17 and CGI-scale) to give us an early glimpse on the drug's proof of concept in these diseases.

SAGE-547 phase 3 allows higher dose retreatment, expect data mid/2H16

The phase 3 STATUS trial with SAGE-547 is to begin mid-2015 (data mid/2H16), and allows higher dose retreatment if patients do not respond to initial 547 or placebo treatment. We believe this is interesting as patients may respond to higher dosages of the study drug, allowing for better response rates without sacrificing safety in the efficacy endpoint, especially since the side effect profile has been relatively clean thus far. Similar to phase 1/2 study, the trial will examine "evaluable" patients due to severity of underlying disorders, effectively an mITT type evaluation. Importantly, we do not believe this will affect the data in its entirety since $\sim 90\%$ of patients will be considered "evaluable."

SAGE-217 high-value oral asset in orphan epilepsies

Second-generation SAGE-217 is currently on track for phase 1 study initiation by year end 2015, potentially in Dravet syndrome. Preclinical studies have already shown favorable selectivity and PK profile of the drug in seizure models. We look forward to additional updates for the company on the exact indication (i.e. Dravet syndrome), which could blend well with the company's current pipeline.

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Target Price / Valuation Methodology:

SAGE Therapeutics - SAGE

Our price target of \$58 is based on an average of our NPV and P/S valuations. Our NPV valuation estimates a \$41 value for the stock, and our P/S valuation estimates a \$75 value for the stock.

Risks to achieving Target Price / Valuation:

SAGE Therapeutics - SAGE

Clinical trials for SAGE-547, 689, and 217 may ultimately fail, resulting in substantial downside to our estimates and price target. SAGE currently has no products approved by FDA or European regulatory agencies and has no revenues at present. Also, the exact number of patients suffering from super-refractory status epilepticus and other subsets of status epilepticus is not known. The actual number of SRSE patients may be smaller than modeled, which could result in difficulty enrolling clinical studies and longer clinical timelines. Smaller patient numbers could also result in lower revenues than our current estimates. Later-stage clinical trials for SAGE-547 may fail despite encouraging initial data from emergency use cases, resulting in lack of clinical approval, revenues, and downside to our price target. In addition, safety signals may emerge in Phase 1/2 and Phase 3 studies that were not seen in the initial emergency use cases. Safety signals could prevent FDA approval if serious. SAGE utilizes third parties, or clinical research organizations, to conduct its clinical studies for SAGE-547. Should these organizations conduct poor quality control, poor selection of clinical investigators, or improper statistical analysis, SAGE shares could be adversely impacted. Also, if the clinical research organization does not recruit the studies in a timely fashion, investors may become disappointed, creating downward pressure on the stock. Even assuming regulatory approval, SAGE's products may not perform well in the marketplace, resulting in lower revenues. If the pace of the launch is too slow. investors may be disappointed, and shares may be under pressure. Competitive products may emerge that generate better clinical data versus SAGE's pipeline. At present, SAGE's principal competitor is Marinus Pharmaceuticals, which is developing a reformulated form of Ganaxalone. a known GABA positive allosteric modulator neuroactive steroid, for potential treatment of drug-resistant partial complex seizures and fragile X syndrome. Also, many of SAGE's competitors have substantially more resources to fund clinical development, and may do so in a faster and/or more effective manner. SAGE is also likely to need substantial additional funding going forward, potentially creating downward pressure related to financing. Research and development costs may be higher than we have anticipated, requiring additional capital and potential dilution. SAGE expects to continue to incur substantial operating losses for the foreseeable future. The company may never become profitable, or profitability may take much longer than originally anticipated, disappointing some investors and resulting in downside to the share price.

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Global Stock Ratings (as of 05/14/15)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	580	58.00%	32.41%
Hold	336	33.60%	15.77%
Sell	39	3.90%	5.13%
Speculative Buy	45	4.50%	55.56%
	1000*	100.0%	

^{*}Total includes stocks that are Under Review

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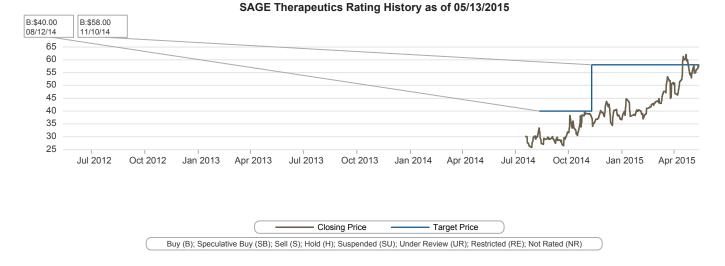
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