

Today's Changes	Annual EPS	Annual Revenue	Rating/Target
	2014(1.84) from (1.45)	No changes	No changes
	2015(1.51) from (1.64)		

SAGE Therapeutics

SAGE : NASDAQ : US\$29.05

BUY

Target: US\$40.00

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COMPANY STATISTICS:

Forecast Return:	38%
Market Cap (M):	US\$696
52-week Range:	24.25 - 34.88
Avg. Daily Vol. (000s):	432.1

EARNINGS SUMMARY:

FYE Dec		2014E	2015E	2016E
Revenue (M):	Q1	0.0A	0.0	-
	Q2	0.0A	0.0	-
	Q3	0.0	0.0	-
	Q4	0.0	0.0	-
Total		0.0	0.0	0.0
EPS:	Q1	(3.70)A	(0.39)	-
	Q2	(4.57)A	(0.35)	-
	Q3	(0.30)	(0.37)	-
	Q4	(0.42)	(0.40)	-
Total		(1.84)	(1.51)	(1.54)

SHARE PRICE PERFORMANCE:



Source: Interactive Data Corporation

COMPANY DESCRIPTION:

SAGE Therapeutics is a development/clinical stage biopharmaceutical company founded in 2010 that is focused on developing and commercializing drugs to treat central nervous system (CNS) disorders where no effective or FDA approved options exist.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

SAGE-547 CHANCE OF SUCCESS FAVORABLE IN TOUGH DISEASE

Investment highlights

Estimate \$980M US peak sales for SAGE-547

We estimate \$980M US peak sales from ~13,300 SRSE patients, representing 55% of total super refractory status epilepticus (SRSE) patients and 13.8% of all ~96,000 patients treated for status epilepticus in the hospital. We assume a cost of ~\$75,000 per patient annually, which we believe is appropriate for the hospital setting given these patients are critically ill and are on last lines of therapy.

SAGE-547 has clear mechanism of action

SAGE-547's mechanism is well understood, upregulating GABA at two synapses ($\alpha 1$ and $\alpha 4$) while current therapies only hit GABA at $\alpha 1$ receptor. We believe this gives the drug an advantage over other therapies because the dual interaction can potentiate stronger GABA duration, leading to improved seizure control.

Current therapies remain ineffective

Current therapies remain ineffective in controlling SRSE (response rates <40%) or have intolerable side effects, giving SAGE-547 a low risk of penetrating in this market. Additionally, we want to emphasize the severity of this disease where patients in the ICU carry a mortality risk of close to ~50%, making this an area of high unmet medical need.

Expect positive SAGE-547 weaning data in December

We expect positive data for SAGE-547 when patients are weaned off drug and brought out of coma in December for at least n=10 patients. Previous data suggested resolution of SRSE in 9/10 patients, whereas new data will discuss weaning patients off drug and reversing coma.

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ESTIMATE \$980M US PEAK SALES FOR SAGE-547

We assume \$980M US peak sales for SAGE-547 by 2021 based on ~55% share of super-refractory status epilepticus (SRSE) at a cost of ~\$75,000 in 2021. We believe that the cost is justified in the hospital setting, where expensive drugs are seldom used, given that this patient population is critically ill with high mortality risk. In addition, there is a significant lack of effective treatments to control the ongoing seizure and coma (see below for current treatment paradigm). In total, we project ~96,000 patients will be diagnosed with status epilepticus by 2020 based on Hospital Care Utilization Project and Agency for Healthcare Research & Quality. Front line therapy remains conventional benzodiazepines, which remains sufficient for 60% of patients for seizure control. However, if front line therapy does not control seizures within 30 minutes (~58,000 patients), the patient is diagnosed as established status epilepticus. These patients are treated with IV antiepileptics (phenytoin, phenobarbital, or VPA), but case control and retrospective data shows benefit in only about 40% of the patients, leaving about ~35,000-40,000 patients requiring third line treatment with general anesthesia (propofol, midazolam, thiopental) in the ICU. Unfortunately, retrospectively chart reviews suggest efficacy of 50-60% before finally being diagnosed with SRSE (~24-25,000 patients).

With this final SRSE patient population, we model ~55% share for SAGE-547 in SRSE by 2021, or ~13,300 patients on treatment. By assuming a ~\$75,000 per patient at launch, a 2.5% annual price increase, and 95% adherence since the drug will be administered in the hospital setting, this results to an effective cost of ~\$79,000 per patient by 2021. We assume a moderate discount of ~6% for the hospital setting, resulting in an estimate of ~\$980M US peak sales in 2021.

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Figure 1: SAGE-547-US revenue build

Status Epilepticus	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
US Market										
Incidence - Non-hospital	153,015	154,545	155,318	156,094	156,875	157,659	158,448	159,240	160,036	160,836
% failing benzodiazepines	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Incidence - hospital	91,809	92,727	93,191	93,657	94,125	94,596	95,069	95,544	96,022	96,502
% failing benzodiazepines	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Second-line status epilepticus	55,085	55,636	55,914	56,194	56,475	56,757	57,041	57,326	57,613	57,901
% failing second-line	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Refractory Status Epilepticus	38,560	38,945	39,140	39,336	39,532	39,730	39,929	40,128	40,329	40,531
% failing 3rd-line	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Super-refractory status epilepticus	23,136	23,367	23,484	23,601	23,719	23,838	23,957	24,077	24,197	24,318
% share SAGE-547					0%	5%	20%	35%	55%	60%
Patients receiving SAGE 547	-	-	-	-	-	1,192	4,791	8,427	13,309	14,591
Cost per treatment					\$75,000	\$76,875	\$78,797	\$80,767	\$82,786	\$84,856
adherence					95%	95%	95%	95%	95%	95%
Cost per patient			-	-	71,250	73,031	74,857	76,728	78,647	80,613
SAGE-547 revenues										
SAGE-547 demand (\$000's)	-	-	-	-	-	87,046	358,674	646,589	1,046,677	1,176,227
Inventory build / (draw down)	-	-								
Discounts & rebates	-	-		\$	- \$	(5,223) \$	(21,520) \$	(38,795) \$	(62,801) \$	(70,574)
US SAGE-547 revenues (\$000's)	-	-	-	-	-	81,823	337,154	607,793	983,876	1,105,653

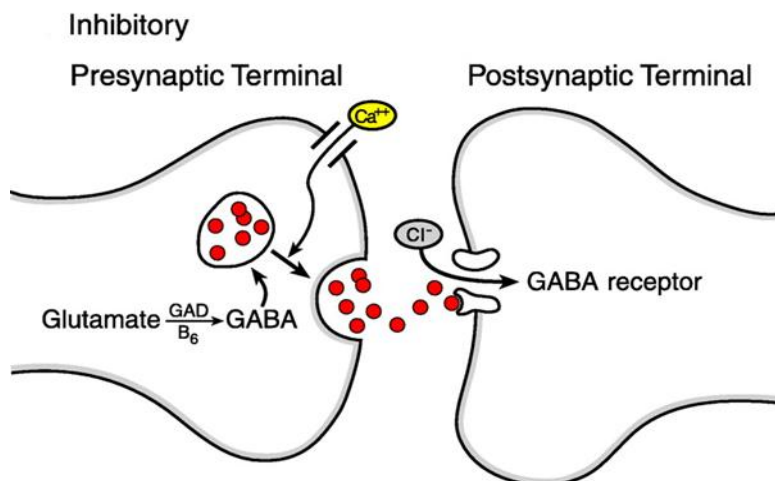
Source: Company reports and Canaccord Genuity estimates

UNIQUE MECHANISM OF ACTION KEY FOR SRSE MARKET PENETRATION

Super-refractory status epilepticus not only affects patients post severe trauma, but also previously healthy patients as well. It is hypothesized that receptors on the surface of axons are in a highly dynamic state during SRSE, and the overall effect is a reduction in the number of functional GABA receptors in the cells to terminate the seizure. As GABA remains the principal inhibitory transmitter, the reduction in GABAergic activity remains as one of the most significant reasons for seizure persistence. There have been many proposed reasons for loss of GABAergic activity during SRSE, including loss of GABA receptor density to uptake the GABA neurotransmitter, inhibitory GABA-mediated currents, or increase in the number of excitatory glutaminergic neurotransmitters/receptors overcoming the GABA receptors (Lamsa et al, 2003). Additionally, it has been proposed that other cellular events, including mitochondrial failure, inflammatory

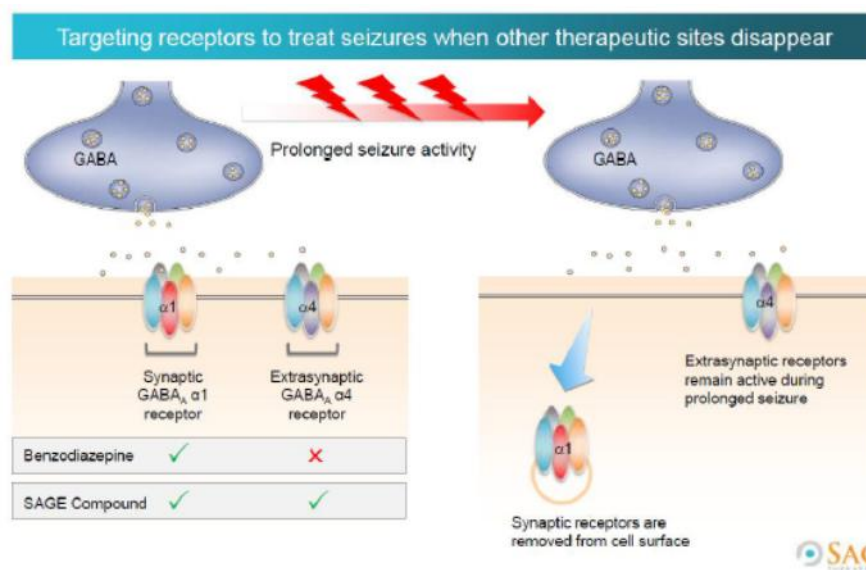
disease, or penetration of excitatory chemicals into the blood brain barrier can potentiate the seizure activity (Cock et al 2002) (Tan et al 2010). However, one thing remains certain: upregulation of the inhibitory GABA receptor remains pivotal to seizure control (Figure 2). Despite multiple drugs currently available on the market that tries to upregulate GABA, most patients still remain refractory to these therapies. Therefore, the reason for treatment failure lies not on the wrong target, but rather on the lack of upregulation potency of the GABA receptor itself from these current therapies (Lamsa et al 2003).

Figure 2: GABA receptor uptake



Source: Journal of Postgraduate Medicine

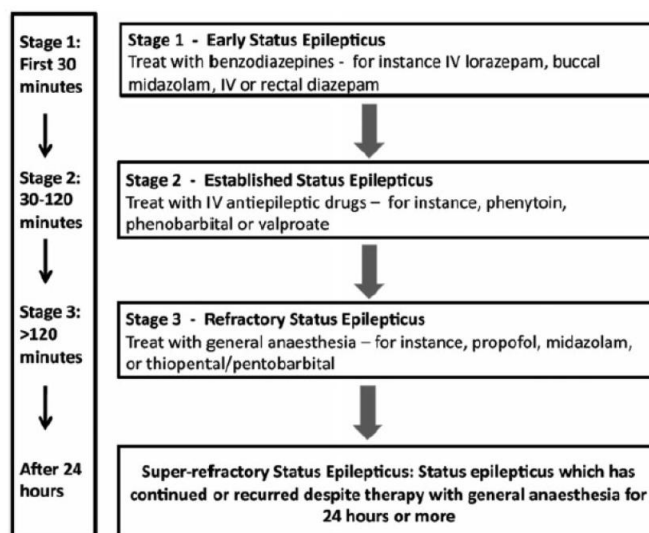
SAGE-547 targets the GABA receptor in a different way compared to benzodiazepines. As seen in Figure 2, resistance to current benzodiazepine treatment is thought to be related to the removal of GABAA1 synaptic receptor during seizure activity. Because benzodiazepines only bind to GABA at the $\alpha 1$ synapse, efficacy remains short lived and desensitization occurs relatively soon after status epilepticus. SAGE-547 addresses the problem by binding at not only the $\alpha 1$ synapse, but also at the $\alpha 4$ extra-synaptic receptor for a more durable GABA receptor upregulation. This improved mechanism of action could explain why SAGE-547 has been shown to be even efficacious in SRSE patients who were previously refractory to benzodiazepines.

Figure 3: SAGE mechanism of action

Source: Sage Therapeutics

CURRENT THERAPIES LACK EFFICACY, SIDE EFFECTS HIGH

When patients are diagnosed with status epilepticus, they have 24 hours to break the seizures before patient becomes SRSE. The primary aim of treatment in the earlier phases of status epilepticus is to control seizures while preventing initial excitotoxicity that may cause cerebral damage. However, once patients are in SRSE, the excitotoxicity may have already occurred. The mortality rate of status epilepticus increases the longer the episode continues, with death being due to complications from the seizure itself or from the harsh treatment

Figure 4: Treatment of status epilepticus

Source: Shorvon S. Brain 2011

Anesthesia clouded with side effects

Anesthesia remains the backbone of therapy for SRSE, though no specific agent in the class is labeled as first line. However, each agent has its own individual side effects that limit their long term use in SRSE patients. Barbiturate anesthesia (thiopental and pentobarbital) enhances the action of GABA receptors and theoretically have neuroprotective effects. However, they exhibit zero degree PK and due to the rapid redistribution of the drug, there is a significantly long half-life of the drug, creating a huge disadvantage if trying to wean the patient off the drug. Secondly, barbiturates can cause severe hypotension and cardiorespiratory depression, sometimes requiring additional pressors.

Midazolam also has GABA enhancing actions with much shorter half-life than barbiturates, making this drug suitable for prolonged infusions without accumulation. However, rapid and acute tolerance can develop (as soon as 1 day of use) and thus carries the risk of relapse. Breakthrough seizures were reported to be as high as 47-57% (Singh 2002) (Morrison (2006). Additionally, there is risk of renal and hepatic toxicity with midazolam.

Propofol has similar MOA as the other anesthesia agents, with fast onset and offset PK profiles. However, propofol infusion syndrome (PRIS) has been reported, with severe symptoms including metabolic acidosis, lactic acidosis, rhabdomyolysis, hyperkalemia, and renal failure. Additionally, prolonged propofol infusion increases the risk of pancreatitis and hypertriglyceridemia. Mayo Clinic noted three unexplained cardiorespiratory arrests, with 2 deaths and 11 patients with PRIS, forcing the institution to remove propofol from their treatment protocols (Cooper 2009).

Unlike the previous anesthetics mentioned above, **ketamine** does not have a role in GABA receptors, but rather inhibits NMDA receptors (an excitatory receptor up regulated during seizures). Advantages include a rather clean safety profile and

possible neuroprotective effects from NMDA inhibition, but lack of experience and clinical data limits its distribution.

Antiepileptics without clear indication

In SRSE, physicians administer antiepileptic drugs in combination with anesthesia, though no data has ever shown to produce any increased benefit. It does have a role once anesthesia is weaned off for seizure control. The drugs commonly used include phenytoin, phenobarbital, VPA...etc., but no consensus exists on which therapy is superior.

Significant unmet medical need, positive for SAGE-547

Magnesium infusion, pyridoxine, steroids, ketogenic diet, emergency neurosurgery, and electrical therapies have also been reported in the literature, though minimal success. Therefore, lack of effective treatment for SRSE makes this disease serious condition and an area of high unmet need. The mortality rate is substantial, reported in various series about 30-50%. Results from Phase 1/2 trials for SAGE-547 are currently promising with all patients showing response when previously failed one or more weaning attempts. Additionally, the clean toxicity profile of SAGE-547 to date leads this drug as a best in therapy for SRSE patients.

PHASE 1/2 POSITIONED FOR SUCCESS; EXPECT FULL RESULTS DECEMBER 5 AT AES

SAGE is currently conducting a Phase 1/2 program in patients with SRSE (n=10), with full data to be presented YE14, including results when patients are weaned off drug. In this trial, patients are enrolled if they continue to have status epilepsy after ≥ 24 hours despite 1st and 2nd line therapy AND failed to control seizures after 24 hours while under general anesthesia. During the first day, patients are under seizure suppression with a continuous IV antiepileptic and are given SAGE-547 as a one-hour loading dose followed by a maintenance infusion. After 48 hours of SAGE-547 dosing, the continuous IV AED will be weaned while treatment with SAGE-547 continues. After four days of treatment, the SAGE-547 dose will be tapered and discontinued over 24 hours (see figure below).

Figure 5: SAGE-547 trial design



Source: SAGE therapeutics

Secondary endpoint results key, expect in December 2014

We expect positive results for the secondary endpoint for SAGE-547 in terms of weaning patients off the drug and bringing them out of coma to be presented in December. The secondary endpoint is defined as cessation of seizure activities while off SAGE-547. Prior results showed cessation of status epilepticus when SAGE-547 was given, which is encouraging, but data for drug weaning have not yet been made available.

Prior data positive and encouraging

Preliminary Phase 1/2 data shows promising results in SRSE, with 9/10 patients showing cessation of status epilepticus after administration of SAGE-547. To date, n=10 patients with SRSE who failed one or more anesthesia weaning attempts were placed on SAGE-547, n=4 from the Phase1/2 trial, and n=6 from emergency use. All four patients in the Phase1/2 trial met the primary endpoint, with two patients achieving complete dechallenge of SAGE-547 (secondary endpoint). Figure 6 describes the ICU duration and etiology of the four patients currently treated. Analysis of patient #2 was interesting, since Landau-Kleffner syndrome patients, a dangerous infantile acquired epileptic aphasia, usually have extremely poor outcomes. This patient was hospitalized in the ICU for nearly three weeks, and administration of SAGE-547 was the only therapy that broke her seizures.

Figure 6: SAGE-547 Phase 1/2b preliminary data

Patient	#1	#2	#3	#4
Age / Sex	65 / Male	14* / Female	33 / Female	36 / Male
ICU Duration	12 days	11 days	21 days	4 days
Failed 1 or more Weaning Attempts	Yes	Yes	Yes	Yes
Etiology	Subdural Hematoma	Landau-Kleffner Syndrome	HIV / Toxoplasmosis	Seizure Disorder / Pneumonia
Drug-related SAEs	None	None	None	None
Steady-state Plasma Levels >80nM	Yes	Yes	Yes	Pending
Key Efficacy Endpoint Met	Yes	Yes	Yes	Yes

*FDA agreement to enroll out of age range on single use basis

Comments

- Study designed with broad inclusion criteria
- Key efficacy endpoint evaluated on SAGE-547 by the need to re-instate IV general anesthesia
- 4 of 4 patients met key efficacy endpoint
- Patient #4 remains enrolled in the three-week follow-up period
- Positive dechallenge data in 2 patients

Protocol Amendment Planned

- Amendment planned to permit increased dose and duration of treatment



Source: SAGE Therapeutics

SAGE-547 has also been administered in n=6 emergency use patients (Figure 7), with resolution of SRSE in 5/6 patients. ICU duration was >30 days in three patients, >60 days in two patients, and >90 days in one patient. Importantly, the patient where SRSE was not resolved did not achieve steady state plasma levels of the drug >80nM. SAGE is currently working to amend the trial protocol in order to enable higher dosing if needed.

Figure 7: SAGE-547 emergency use patients**Super-Refractory Status Epilepticus – Emergency-Use Experience**

Patient	#1	#2	#3	#4	#5	#6
Age / Sex	23 / Male	11 / Female	28 / Male	2 / Female	17 months / Male	14 / Female
ICU Duration	> 90 days	> 60 days	> 60 days	> 30 days	> 30 days	> 30 days
Failed Multiple Weaning Attempts	Yes	Yes	Yes	Yes	Yes	Yes
Etiology	Unknown	Autoimmune (anti-Thyroid / Anti-GAD)	Unknown	Presumed Metabolic Disorder	Presumed Metabolic Disorder	Progressive myoclonic epileptic encephalopathy
Drug-related SAEs	None	None	None	None	None	None
Steady-state Plasma Levels >80nM	Yes	Yes	Yes	Yes	No	Yes
Status Epilepticus Resolved	Yes	Yes	Yes	Yes	No	Yes
Time from Discontinuation of SAGE-547 to Resolution of SRSE	Concurrent	Concurrent	3 days	Concurrent	N/A	3 days

Source: Canaccord Genuity, Inc.

We believe SAGE-547 is positioned for success given the positive results from these four preliminary patients, a positive leading into FDA filing for a Phase 3 trial in H1/15. Additionally, the trial excludes very sick patients with low chance of survival, like severe traumatic brain injury or SRSE due to anoxic/hypoxic encephalopathy, giving favor for an expected positive outcome.

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Figure 8: SAGE income statement

	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues													
SAGE-547													
US							-	-	-	-	81,823	337,154	607,793
Ex-US							-	-	-	-	51,888	52,148	209,633
Ex-US royalty									-	-	8,821	8,865	35,638
Total			-	-	-	-	-	-	-	-	90,644	346,019	643,431
Income Statement													
Total Revenue	-	-	-	-	-	-	-	-	-	-	90,644	346,019	643,431
COGS	-	-	-	-	-	-	-	-	-	-	9,064	34,602	64,343
Gross Profit	-	-	-	-	-	-	-	-	-	-	81,580	311,417	579,088
Operating Expenses													
Research and development	7,229	14,357	4,173	4,381	6,325	9,747	24,626	39,236	41,689	42,996	47,760	57,785	71,508
General and administrative	2,402	3,922	1,617	1,807	1,825	1,843	7,092	7,559	7,687	7,764	32,806	35,706	38,893
Total Operating Expense	9,631	18,279	5,790	6,188	8,150	11,591	31,718	46,795	49,376	50,760	80,565	93,491	110,401
EBITDA													
Operating income	(9,631)	(18,279)	(5,790)	(6,188)	(8,150)	(11,591)	(31,718)	(46,795)	(49,376)	(50,760)	1,015	217,926	468,687
Interest (expense) income, net	-	1	-	1	1	1	3	8	3	8	3	8	3
Other income (expense), net	(1)	(3)	-	(5)	(5)	(5)	(15)	(40)	(15)	(40)	(15)	(40)	(15)
Pre-tax income (GAAP)	(9,632)	(18,281)	(5,790)	(6,192)	(8,154)	(11,595)	(31,730)	(46,827)	(49,388)	(50,792)	1,003	217,894	468,675
Pre-tax income (non-GAAP)													
Taxes (GAAP)	-	-	-	-	-	-	-	-	-	-	371	80,621	173,410
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Accretion of redeemable convertible preferred	(4)	(7)	(326)	(1,577)									
Net Income (GAAP)	(9,637)	(18,288)	(6,116)	(7,769)	(8,154)	(11,595)	(33,633)	(46,827)	(49,388)	(50,792)	632	137,273	295,265
GAAP EPS (diluted)	(\$8.62)	(\$12.26)	(\$3.70)	(\$4.57)	(\$0.30)	(\$0.42)	(\$1.84)	(\$1.51)	(\$1.54)	(\$1.44)	\$0.02	\$3.21	\$6.29
Diluted shares	1,118	1,492	1,653										
Pro forma - diluted shares		9,514	16,774	1,701	27,270	27,543	18,322	30,973	32,084	35,292	38,821	42,703	46,974
Pro forma EPS (diluted)		(\$1.92)	(\$0.36)	(\$4.57)	(\$0.30)	(\$0.42)	(\$1.84)	(\$1.51)	(\$1.54)	(\$1.44)	\$0.02	\$3.21	\$6.29

Source: Company reports and Canaccord Genuity estimates

Figure 9: Valuation

Product	Peak Sales / Royalties (\$MM)	Year	NPV at launch	Probability Adjustment	Current Value (\$MM)	Value / Share
SAGE-547						
US	\$984	2020	\$2,148	55%	\$853	\$32
Ex-US - royalty	\$82	2024	\$175	55%	\$69	\$3
Total SAGE-547 revenues	\$1,066				\$922	
Total Product Value					922	\$34
Cash					149	\$6
Total Equity Value					1,071	\$40
Shares Outstanding (MM)					27	
Risk-Free Rate	3.0%					
Beta	1.8					
Risk Premium	4%					
Discount Rate	10%					

Source: Canaccord Genuity

Investment risks

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.

APPENDIX: IMPORTANT DISCLOSURES

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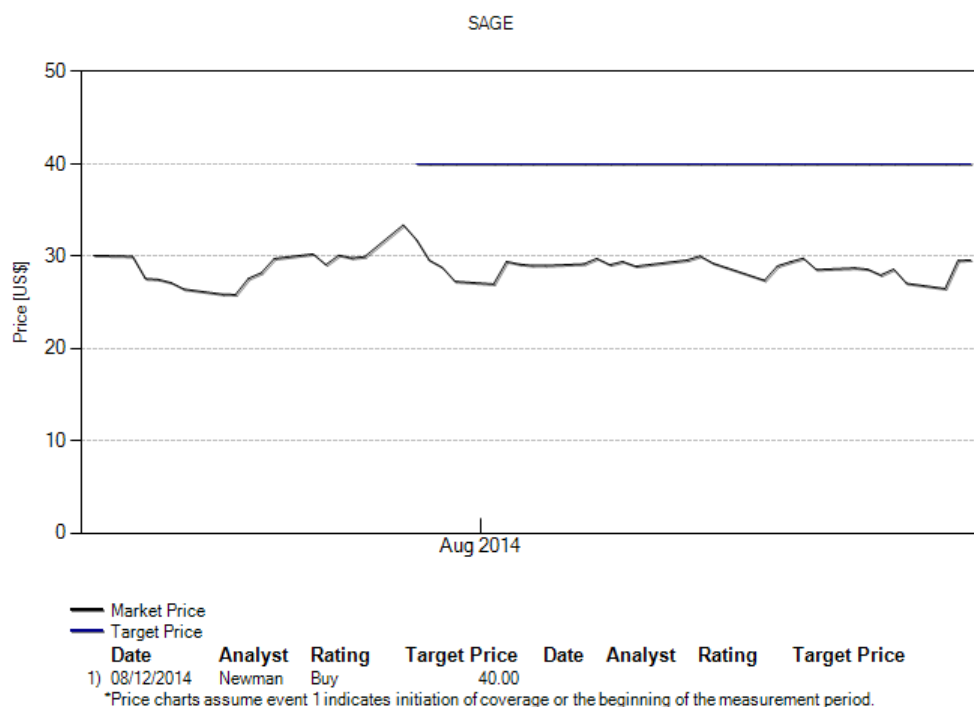
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Site Visit:

An analyst has not visited SAGE Therapeutics' material operations.

Price Chart:***Distribution of Ratings:**

Global Stock Ratings
(as of 3 July 2014)

Rating	Coverage Universe		IB Clients
	#	%	
Buy	602	61.2%	38.2%
Speculative Buy	49	5.0%	55.1%
Hold	290	29.5%	13.1%
Sell	41	4.2%	7.3%

984

100.0%

*Total includes stocks that are Under Review

**Canaccord Genuity
Ratings System:****BUY:** The stock is expected to generate risk-adjusted returns of over 10% during the next 12 months.**HOLD:** The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months.**SELL:** The stock is expected to generate negative risk-adjusted returns during the next 12 months.**NOT RATED:** Canaccord Genuity does not provide research coverage of the relevant issuer.

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Risk Qualifier:

SPECULATIVE: Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

Canaccord Genuity Research Disclosures as of 26 September 2014

Company	Disclosure
SAGE Therapeutics	1A, 2, 3, 5, 7

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 - B. non-investment banking securities-related services.
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