SAGE Therapeutics

SAGE : NASDAQ : US$33.40

BUY

Target: US$40.00

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COMPANY STATISTICS:

Forecast Return:	17%
Market Cap (M):	US$800.3
52-week Range:	24.25 - 34.88
Avg. Daily Vol. (000s):	432.1

EARNINGS SUMMARY:

FYE Dec		2014E	2015E	2016E
P/Sales:		NM	NM	NM
P/E:		NM	NM	NM
Revenue (M):	Q1	0.0	0.0	-
	Q2	0.0	0.0	-
	Q3	0.0	0.0	-
	Q4	0.0	0.0	-
Total		0.0	0.0	0.0
EPS:	Q1	(3.70)	(0.44)	-
	Q2	(0.26)	(0.38)	-
	Q3	(0.34)	(0.40)	-
	Q4	(0.48)	(0.42)	-
Total		(1.45)	(1.64)	(1.68)

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 unless otherwise noted.

Life Sciences -- Biotechnology

DRUG FOR RARE EPILEPSY COULD TOP $980M IN US; INITIATE COVERAGE WITH BUY RATING, $40 PRICE TARGET

Investment highlights

SAGE-547 addresses serious seizure disorder; $980M US peak
SAGE-547 could peak at ~$980M in the US assuming approval for super-refractory status epilepticus, a serious seizure disorder with no FDA-approved treatments. We expect orphan designation and full economics to SAGE in the US, providing an attractive growth opportunity.

Phase 1/2 SAGE-547 data YE14 key catalyst
We expect positive Phase 1/2 data for SAGE-547 by YE to propel shares higher and inform the Phase 3 design. In an emergency-use setting and early Phase 1/2 work, 8/10 patients were successfully treated for super-refractory status epilepticus, a very strong result predicting success in the full Phase 1/2 dataset and in Phase 3.

Additional pipeline assets provide potential for multi-leg growth
SAGE has two additional drugs (689, 217) providing additional long-term growth potential. Both drugs target GABA receptors and have shown positive pre-clinical data. These drugs will qualify for NCE status, a rarity in central nervous system drugs.

Establishing $40 price target, BUY
We are establishing a $40 price target based on a probability adjusted net present value and $980M US peak sales for SAGE-547 by 2021.

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INVESTMENT THESIS

We are initiating coverage on SAGE Therapeutics with a BUY rating and $40 price target based on expected clinical success and FDA approval for the company's sole asset SAGE-547 for the treatment of super-refractory status epilepticus. We view SAGE as a high growth, high margin story with multiple growth drivers in its three pipeline assets. SAGE is targeting serious diseases with no approved therapies, which should allow for high pricing, resulting in very attractive operating and net margins for investors. Also, super-refractory status epilepticus is treated at only ~200 specialized epilepsy centers in the US, which should allow for a small salesforce, resulting in low SG&A costs. Finally, all three of SAGE's assets that are being developed in epilepsy are likely to require only small salesforces.

SAGE-547 has generated interesting data in six patients to date in super-refractory status epilepticus (SRSE), suggesting success in the company's ongoing Phase 1/2 study. Six patients were treated with the drug under emergency use Investigational New Drug (IND) applications, with five achieving resolution of SRSE either during the course of or soon after treatment. These data suggest the Phase 1/2 trial will be successful in resolving SRSE in a larger number of patients. Because the disease is so severe, we expect rapid commercial uptake assuming FDA approval. We believe that clinical development is de-risked as SAGE-547 has a similar mechanism of action to currently used benzodiazapines. Both benzodiazapines and SAGE-547 target the synaptic $GABA_A$ α1 receptor, known to be involved in seizures. However, SAGE-547 also targets the extrasynaptic $GABA_A$ α4 receptor, whereas benzodiazapines do not.

SAGE has two additional assets in the pipeline, providing the potential for long-term, multi-leg growth, a rarity among small cap biotechnology companies, especially those focused on central nervous system disorders. SAGE-689 is a new chemical entity (NCE) targeting second-line status epilepticus, to be used in combination with current treatments. The drug has shown efficacy in seizure models, where benzodiazepines fail. SAGE-689 has arrested second-line status epilepticus when given as a single IV dose. SAGE is also developing SAGE-217, an intravenous (IV) and oral drug with a long half-life designed to be used for status epilepticus maintenance and seizure suppression in epilepsies.

In short, we view SAGE as an attractive multi-leg, high margin growth story with high pricing power and known mechanism of action for drugs in development, decreasing risk. We expect SAGE-547 to produce successful Phase 1/2 clinical data, which should drive shares higher going forward.

VALUATION – SETTING $40 PRICE TARGET

We are establishing a $40 price target based on a probability adjusted net present value (NPV) calculation based primarily on SAGE-547. We project US peak sales of ~$980M for SAGE-547 by 2021, and ex-US peak sales of ~$370M by 2022. We model ex-US sales as a ~22% royalty to SAGE and assume all R&D and SG&A costs are covered by a partner. At this time, we do not include value for SAGE-689 or 217, which would represent upside to our current estimates.

Our analysis is based on peak sales projections for SAGE-547, which we estimate using a market build based on published papers, the HCUP database, and other estimates for the market size of status epilepticus. We then estimate COGS, royalties, discounts and rebates, and R&D + SG&A expenses to arrive at operating profit. For SG&A, we assume fully loaded costs at the beginning of the launch, and for R&D, we include costs from the present time until approval, as well as after initial revenues. We assume a 37% tax rate 1-2 years after approval due to expected utilization of non-operating losses. We discount net profit back to the launch date at a rate of 11%, and then apply a probability adjustment of 55% based on the high degree of positive results seen in early Phase 1/2 data.

US SAGE-547 worth $32

We model $32 for SAGE-547 in the US based on ~$980M peak sales by 2021, and a ~55% share of the super-refractory status epilepticus market. Our estimates assume ~24,200 treated super-refractory status epilepticus patients by 2020, pricing of ~$83,000 per treatment based on an initial launch price of $75,000 and 2.5% annual price increases. We assume ~95% adherence as the drug will be administered in the hospital to patients in a coma by healthcare professionals, resulting in an effective price of ~$79,000 per patient. We also assume modest ~6% discounts and rebates, as the treatment will be sold mainly to hospitals.

Ex-US SAGE-547 royalty worth $2

Outside the US, we assume peak sales of ~$370M by 2021 and we model a ~22% royalty to SAGE which assumes commercialization by a partner. Ex-US, we assume a similar number of patients with status epilepticus, ~24,000 by 2021. Our model shows 30% peak share for SAGE-547 by 2021 at a cost of ~$46,000, which assumes a ~35% discount to the US price. We do not assume price increases Ex-US.

Cash adds $6

We add ~$150M in cash to the valuation for SAGE, resulting in ~$40 total value per share. Although we do not always include cash for small, non-profitable biotech companies since they often burn through it, we do include value for SAGE since the cash balance is large and not likely to be depleted near term.

Figure 1: SAGE Therapeutics valuation

Product	Peak Sales / Royalties ($MM)	Year	NPV at launch	Probability Adjustment	Current Value ($MM)	Value / Share
SAGE-547						
US	$984	2020	$2,178	55%	$853	$32
Ex-US - royalty	$82	2024	$173	55%	$67	$2
Total SAGE-547 revenues	$1,066				$920	
Total Product Value					920	$34
Cash					149	$6
Total Equity Value					**1,069**	**$40**
Shares Outstanding (MM)					27	

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	4%
Discount Rate	10%

Source: Canaccord Genuity

COMPANY OVERVIEW

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. Like most biopharmaceutical companies, we do not expect SAGE to be profitable for some time, as the company will spend aggressively on research and development for its clinical pipeline. SAGE is targeting CNS indications where patients are easily identified, initial treatment is usually indicated in the hospital setting, clinical endpoints are well-defined, and development pathways are reasonable from a financial and risk standpoint.

Unlike many companies developing drugs in the CNS space, two of SAGE's three pipeline drugs should qualify as New Chemical Entities (NCEs), providing five years of data exclusivity, and will also have composition of matter patents issued, giving strong protection. The drugs may also qualify for orphan designation, which would provide an additional barrier to entry.

SAGE's pipeline products are targeting a CNS disorder called status epilepticus, a life-threatening condition where the brain is in a state of persistent seizure. SAGE's lead product is SAGE-547, an intravenous product in Phase 1/2 development for the treatment of super-refractory status epilepticus as an adjunctive therapy, combined with drugs currently used. SAGE is also developing SAGE-689 for usage in second line status epilepticus, and SAGE-217 for use in refractory status epilepticus, maintenance therapy in status epilepticus, or in orphan genetic seizure disorders.

PRIMARY RISKS TO OUR OUTLOOK

Risks to our BUY rating and $40 price target include the following:

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.

CATALYSTS

PHASE 1/2 SAGE-547 DATA BY YE14 KEY

We expect positive data for SAGE-547 in super-refractory status epilepticus patients by YE14 from the ongoing Phase 1/2 trial, which should boost shares. Importantly, efficacy data from the study will likely include the number of patients with cessation of status epilepticus by EEG, time to cessation, and also the need to re-instate IV general anesthesia. We would expect SAGE to report that the majority of the patients currently in the study showed cessation of status epilepticus upon administration of SAGE-547, constituting a positive result.

Assuming positive Phase 1/2 data, we would expect SAGE to initiate a pivotal study in early 2015, with data possible later in the year. We expect data in a relatively short time frame because SAGE is testing SAGE-547 in an acute setting.

Figure 2: SAGE expected catalysts

Event	Timing	Drug	Description	Effect	Importance	Notes
Data	YE14	SAGE-547	Phase 1/2 data	↑	Critical	Expect positive data, clear cessation of status epilepticus
Clinical	early 2015	SAGE-547	pivotal trial	↑	High	Expect SAGE to initiate pivotal trial for SAGE-547 in early 2015
Data	mid-2015	SAGE-689	Phase 1 data	↑	High	Expect positive Phase 1 data for SAGE-689

Source: Canaccord Genuity

SAGE-547 CORE ORPHAN DRUG IN SUPER-REFRACTORY SEIZURES

SAGE's lead asset SAGE-547 could represent a substantial improvement in treatment of super-refractory status epilepticus, where no drugs are approved and current therapies are ineffective, holding potential upside to the share price. We believe the relatively small super-refractory status epilepticus patient population of ~25,000 should be readily addressable by a small salesforce, and attractive pricing should create high margins for investors.

ESTIMATE $980M US PEAK SALES FOR SAGE-547

Our model assumes ~$980M US peak sales for SAGE-547 by 2021 based on ~55% share of the super-refractory status epilepticus patients currently treated at a cost of ~$75,000 per patient annually. We assume ~96,000 patients treated in US hospitals diagnosed with status epilepticus by 2020 based on data from the Hospital Care Utilization Project and Agency for Healthcare Research & Quality. Our model assumes that ~60% of these ~95,000 patients fail initial treatment with benzodiazepines, resulting in ~58,000 second-line patients. We assume that ~70% of these second-line patients fail second-line treatment, which often includes re-treatment with benzodiazepines, resulting in ~40,000 refractory status epilepticus patients. Our model estimates that ~60% of refractory patients fail treatment, which often includes anesthesia, resulting in ~24,000 super-refractory status epilepticus patients by 2021s in the US.

We model ~55% share for SAGE-547 in super-refractory status epilepticus by 2021, or ~13,300 patients on treatment. Our pricing assumption is ~$75,000 per patient at launch, followed by 2.5% annual price increases, resulting in a cost of ~$83,000 by 2021. We assume 95% adherence as the drug will be administered in a controlled hospital setting, resulting in an effective cost of ~$79,000 per patient by 2021. We assume moderate discounts and rebates of ~6% given the product will be used in the hospital setting, resulting in ~$980M US peak sales by 2021.

Figure 3: SAGE-547 US revenue build

Status Epilepticus	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
US Market									
Incidence - Non-hospital	153,015	154,545	155,318	156,094	156,875	157,659	158,448	159,240	160,036
% failing benzodiazepines	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
% failing benzodiazepines	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
% failing second-line	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
% failing 3rd-line	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
% share SAGE-547					0%	5%	20%	35%	55%
Patients receiving SAGE 547	-	-	-	-	-	1,192	4,791	8,427	13,309
Cost per treatment					$75,000	$76,875	$78,797	$80,767	$82,786
adherence					95%	95%	95%	95%	95%
Cost per patient			-	-	71,250	73,031	74,857	76,728	78,647
SAGE-547 revenues									
SAGE-547 demand ($000's)	-	-	-	-	-	87,046	358,674	646,589	1,046,677
Inventory build / (drawdown)	-	-							
Discounts & rebates	-	-			$ -	$ (5,223)	$ (21,520)	$ (38,795)	$ (62,801)
US SAGE-547 revenues ($000's)	-	-	-	-	-	81,823	337,154	607,793	983,876

Source: Canaccord Genuity

EX-US SALES MAY REACH $370M BY 2022

We assume that SAGE will partner SAGE-547 ex-US, and value the ex-US revenue stream accordingly. Our model assumes ~$370M ex-US peak sales for SAGE-547, based on similar population estimates versus the US. We model ~96,000 patients treated for status epilepticus in the hospital setting in Europe by 2022. We assume ~60% of these patients fail treatment with benzodiazepines, resulting in ~57,000 second-line patients. For second line, we assume that ~70% of patients fail treatment, resulting in ~40,000 refractory patients. We model ~60% of refractory patients failing treatment, giving ~24,000 super-refractory status epilepticus patients.

We model a slower uptake curve for SAGE-547 in Europe versus the US based on individual country-by-country rollouts. We assume ~35% share for SAGE-547 ex-US by 2022, or ~8,500 patients on therapy. Our cost assumption is a ~35% discount to US pricing, and we do not assume price increases. Similar to the US we assume moderate discounts and rebates at a rate of 6%, resulting in ~$370M ex-US peak sales for SAGE-547 by 2022.

Figure 4: SAGE-547 Ex-US revenue build

Status Epilepticus	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Ex-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%	0%	5%	5%	20%	30%	35%
Patients receiving SAGE 547	-	-	-	-	-	1,192	1,198	4,815	7,259	8,511
Cost per treatment						$48,750	$48,750	$48,750	$48,750	$48,750
adherence						95%	95%	95%	95%	95%
Cost per patient			-	-		46,313	46,313	46,313	46,313	46,313
SAGE-547 revenues										
SAGE-547 demand ($000's)	-	-	-	-	-	55,200	55,476	223,014	336,193	394,187
Inventory build / (drawdown)	-	-								
Discounts & rebates	-	-				$ (3,312)	$ (3,329)	$ (13,381)	$ (20,172)	$ (23,651)
Ex-US SAGE-547 revenues ($000's)	-	-	-	-	-	51,888	52,148	209,633	316,022	370,535

Source: Canaccord Genuity

EMERGENCY-USE, PHASE 1/2 DATA PROMISING FOR SAGE-547

Emergency use data encouraging in n=6 patients

SAGE-547 has also been studied in n=6 patients under emergency use, showing responses in 5/6 patients. The one patient not achieving resolution of super-refractory status epilepticus (SRSE) had low plasma levels of SAGE-547, potentially contributing to the lack of efficacy. Interestingly, each of the n=6 cases of SRSE treated with SAGE-547 via emergency use arose from a different etiology, and patients had been placed in a medically-induced coma. Previous multiple attempts to wean these patients off of anesthesia and re-establish normal brain activity had been unsuccessful.

All emergency-use patients were administered SAGE-547 prior to an additional wean attempt from anesthesia. Three patients (1, 2 and 4 in Figure 5) showed resolution of SRSE during SAGE-547 treatment. Two patients (3 and 6) showed SRSE resolution three days after SAGE-547 treatment was discontinued. Patient #5 had low plasma levels for SAGE-547 and did not show resolution of SRSE.

Figure 5: SAGE-547 – emergency use data

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: SAGE Therapeutics, SEC flings

Phase 1/2 data promising in n=4 patients, trial continuing

Initial Phase 1/2 data for SAGE-547 has been positive in a very difficult to treat patient population, increasing the chances of subsequent data readouts also being positive. Early data from the Phase 1/2 study involving n=4 patients showed that all four patients met the primary endpoint of weaning off anesthesia while SAGE-547 was being administered intravenously. Three patients were subsequently weaned off of anesthesia without re-instating general anesthesia, and one patient experienced recurrence of status epilepticus, requiring reinstitution of general anesthesia (Figure 6).

Figure 6: Phase 1/2 initial results

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**

Source: SAGE Therapeutics, SEC filings

The Phase 1/2 trial is an open-label study enrolling at least n=10 patients diagnosed with SRSE. The study is evaluating safety and tolerability of SAGE-547 in patients with SRSE via electroencephalography (EEG) and electrocardiography (ECG). Efficacy is being measured as a secondary endpoint, indicated by the need to re-institute a continuous intravenous anti-epileptic drug (AED), as well as the duration of observed response. In SAGE's case, the antiepileptic drug that would be re-administered would be anesthesia. Pharmacokinetics of SAGE-547 exposure will also be measured, and plasma pK will be evaluated where appropriate.

Patients will be screened, followed by a four-day treatment period, a one-day dose taper period (24 hours), a two-day acute follow-up period, and then a three week extended follow-up period. Day 1 of treatment: SRSE subjects who are under seizure suppression or burst-suppression with a continuous IV AED will be given a one-hour loading dose of SAGE-547 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 (Figure 6).

Figure 7: SAGE-547 Phase 1/2 trial design

Source: SAGE Therapeutics, SEC filings

Continuous EEG monitoring will occur during screening, continuing until 48 hours after SAGE-547 treatment has completed. Patients will also have follow-up visits for the next three weeks during which safety and functional assessments will be obtained. Importantly, the study will allow patients to continue ongoing treatment with standard of care for SRSE and all other underlying medical conditions.

SAGE has submitted an amendment to FDA for the Phase 1/2 study design that would allow for a higher dose and longer duration of treatment, based on apparent suboptimal dose levels seen in one patient in the emergency use protocol. However, the dose has not yet been escalated in Phase1/2.

CURRENT TREATMENTS LARGELY INEFFECTIVE IN SUPER-REFRACTORY PATIENTS

Patients diagnosed with SRSE are currently treated with a combination of benzodiazepines, anti-epileptic drugs, and anesthesia. However, patients reaching the super-refractory diagnosis have failed all or most of these therapies and have few remaining options. We believe that SAGE-547 represents a potential paradigm-changing drug in the treatment of SRSE.

Front-line therapy dominated by benzodiazepines

Patients diagnosed with status epilepticus in the hospital setting are usually given benzodiazepines as front-line treatment, including lorazepam and diazepam commonly used. Lorazepam was shown to be successful in resolving status epilepticus in up to 65% of patients in the front-line setting.

Second-line therapy involves antiepileptic IV drugs

If front-line therapy is not effective within 30 minutes, physicians will often add treatment with IV anti-epileptic drugs including phenytoin, phenobarbital, or valproate. Controlled data in this setting are limited, but some retrospective reviews suggest 40-50% efficacy. Data are limited and are usually single-center, however.

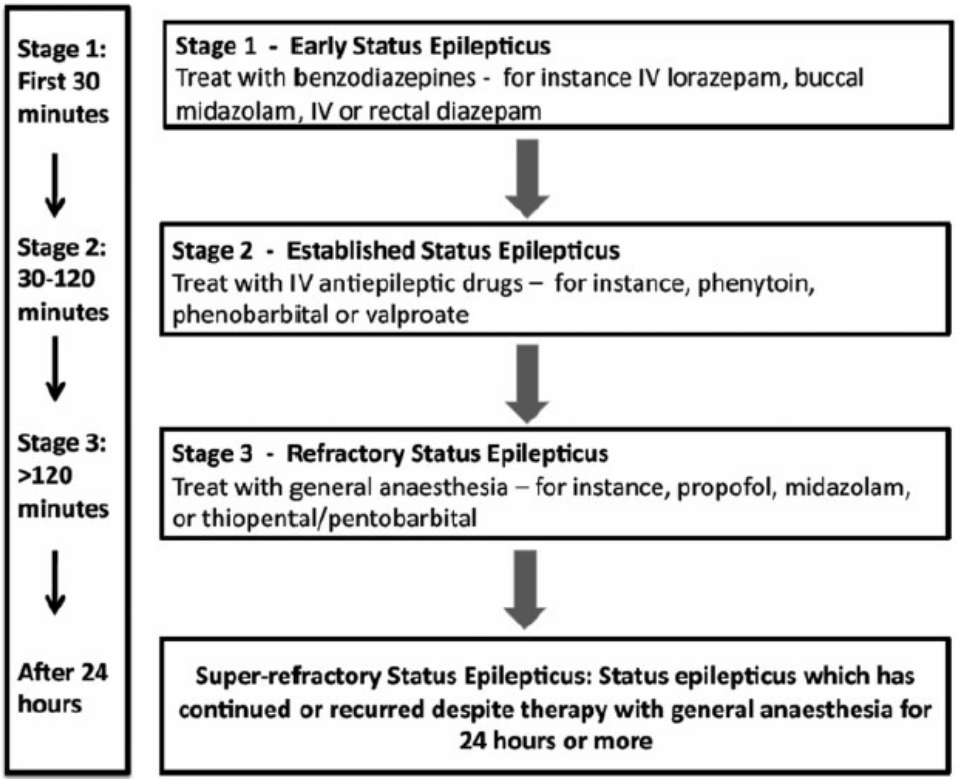
Third-line drugs include general anesthesia

Patients who fail IV anti-epileptic drugs, where treatment is not effective within two hours, often receive general anesthesia, including propofol, midazolam, or thiopental/pentobarbital. Data for efficacy of these agents is lacking. Retrospective chart review suggests efficacy of 50-60%, but relapse often occurs in 40% or so of patients.

Few treatment options for super-refractory patients

When patients cannot be weaned off of anesthesia, they are considered super-refractory, and at this point, few treatment options are available. Physicians will sometimes switch anesthesia to attempt to achieve burst suppression via EEG. Sometimes the underlying cause of status epilepticus can be identified and treated, but often it cannot. Patients are sometimes treated with IV magnesium, although definitive efficacy has never been shown. The treatment is viewed as being safe, however. In addition, some patients receive treatment with steroids, IVIg, and or plasma exchange. Other more drastic measures are available, although not always used, including hypothermia, and neurosurgery in lesional status epilepticus.

Figure 8: Treatment paradigm – status epilepticus



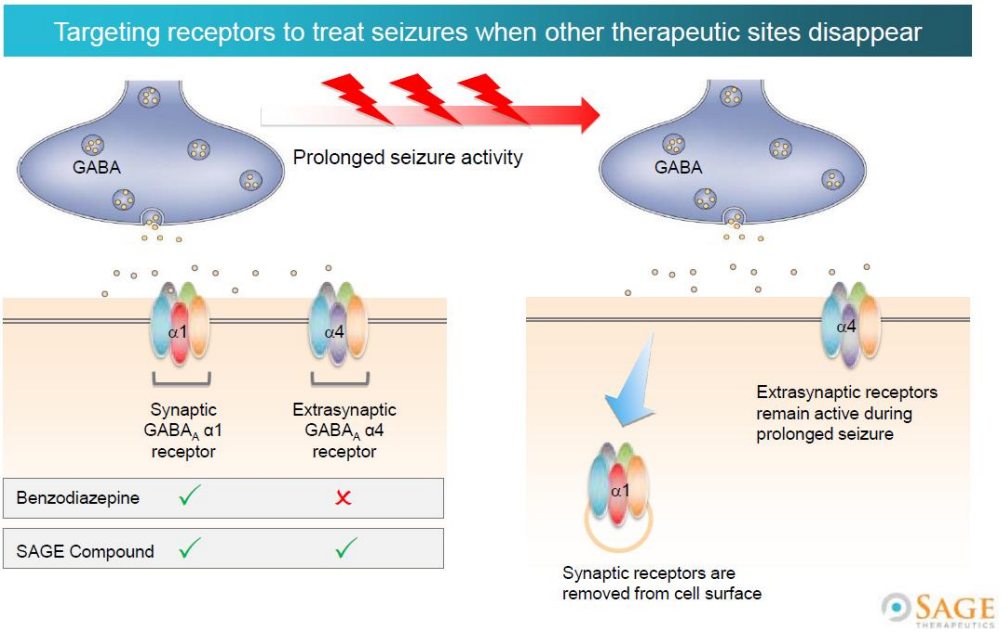
Source: Brain 2011: 134, 2802-2818

SAGE-547 - BEYOND BENZODIAZEPINE MECHANISM

SAGE-547 has a similar, but differentiated mechanism of action versus traditional benzodiazepine drugs, targeting two main receptors versus one for benzodiazepines. Importantly, it is known that patients with status epilepticus eventually become resistant to benzodiazepines. Benzidiazapines act on gamma-aminobutyric acid ($GABA_A$) receptors, where $GABA_A$ is the chief inhibitory neurotransmitter in the central nervous system. This resistance to benzidiazapines is thought to be related to $GABA_A$ synaptic receptors, or α1 receptors being removed from the surface of neurons in the case of prolonged seizure activity. So-called synaptic GABA α1 desensitization occurs relatively soon after status epilepticus onset, rendering benzodiazapines less effective.

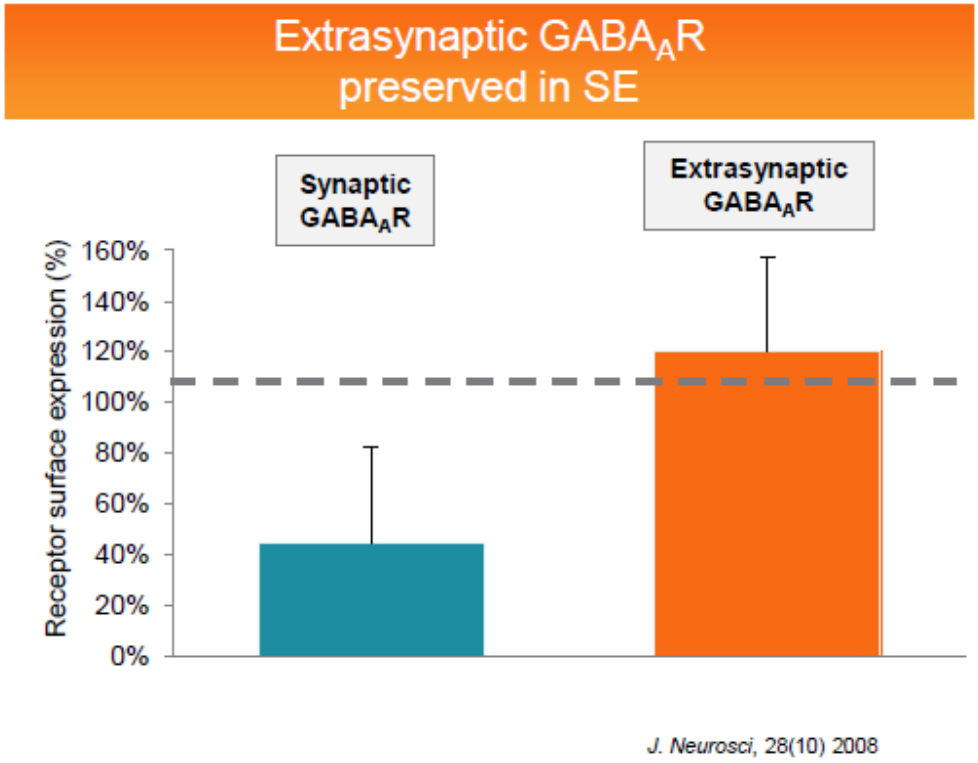
By contrast, SAGE-547 interacts with GABA α4 extrasynaptic receptors in addition to α1 synaptic receptors (Figure 9). The interaction with $GABA_A$ α4 may explain why SAGE-547 appears to be active in super-refractory status epilepticus patients resistant to benzodiazapines. Interestingly, work has shown that extrasynaptic $GABA_A$ α4 receptors are conserved in status epilepticus, whereas synaptic $GABA_A$ receptors are present at a lower level (Figure 10). Additional work has suggested that SAGE-547 is efficacious in a pilocarpine-induced rodent model of status epilepticus after benzodiazapines no longer show efficacy, potentially due to down-regulation of synaptic GABA α1 receptors (Figure 11).

Figure 9: Proposed mechanism of action SAGE-547 vs. benzodiazapines



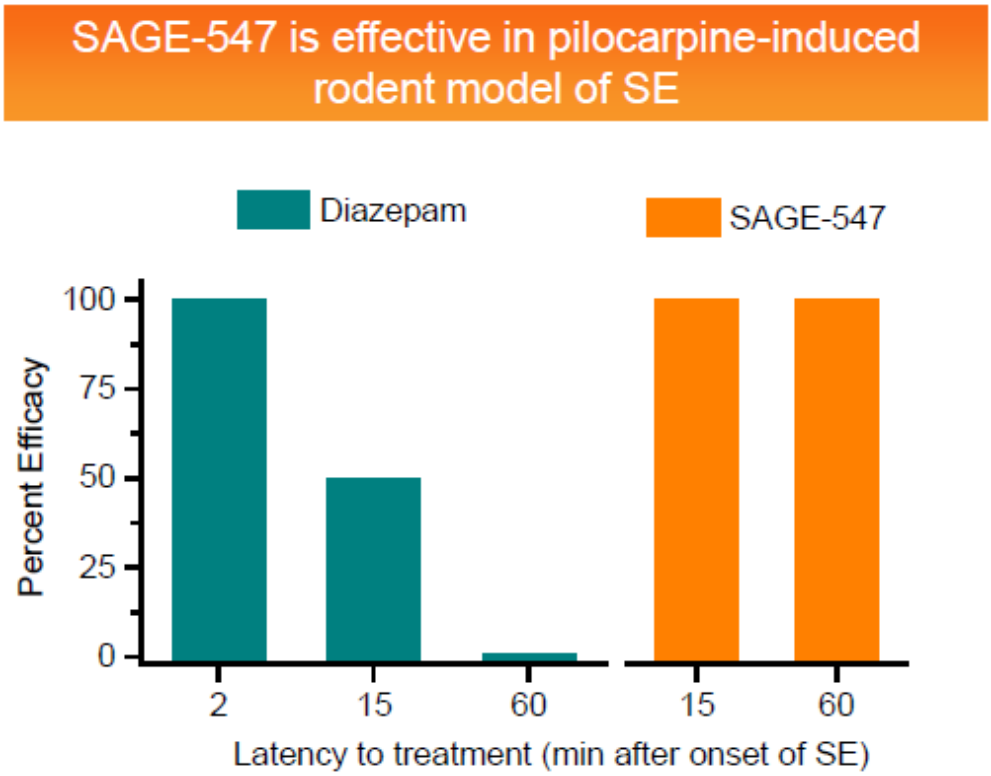
Source: SAGE Therapeutics

Figure 10: Extrasynaptic GABA receptor preservation – status epilepticus



Source: J. Neurosci, 28(10) 2008

Figure 11: SAGE-547 data pilocarpine rodent model status epilepticus



Source: SAGE Therapeutics company presentation

ADDITIONAL PIPELINE ASSETS PROMISING

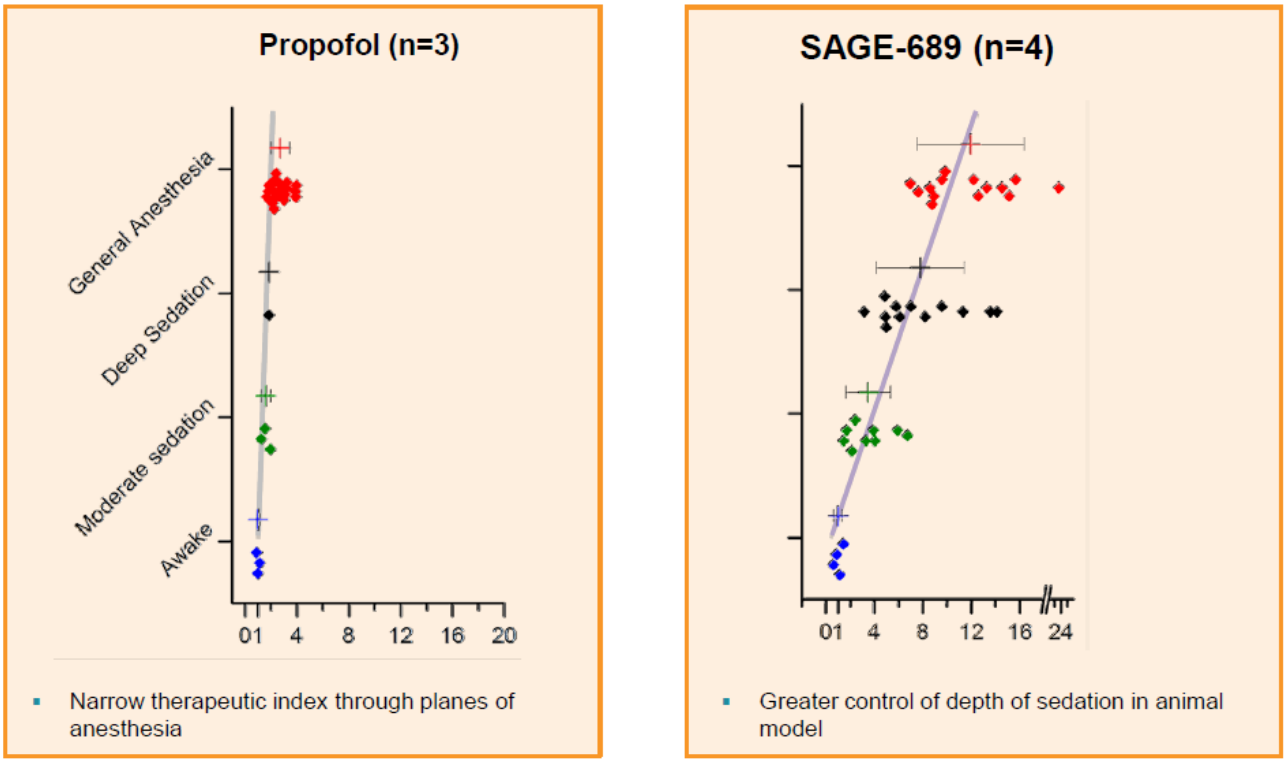
SAGE is developing two additional drugs for treatment of status epilepticus – SAGE-689 and SAGE-217. SAGE-689 is an intravenous therapy also targeting $GABA_A$ and will initially be positioned to treat acute, non-hospital status epilepticus, and to resolve SE in the emergency room in order to prevent admission to the intensive care unit. SAGE is also developing SAGE-217, again targeting $GABA_A$ as an intravenous and oral therapy for status epilepticus maintenance and seizure suppression in epilepsies. The drug may also be used as an intravenous formulation in refractory status epilepticus patients. We currently do not include value for these assets in our model as they are both in pre-clinical development.

SAGE-689 - ADDRESSES SECOND-LINE STATUS EPILEPTICUS IN HOSPITALS

SAGE-689 is being positioned as a drug for use in the hospital to avoid ICU admission for status epilepticus. Importantly, the drug has a wide therapeutic window without inducing anesthesia (Figure 12), which should allow patients to avoid intubation. SAGE-689 also has a short half-life to allow for rapid clearance of the drug and potential discharge from the hospital. SAGE-689 is active at the $GABA_A$ α4 extrasynaptic receptor, and similar to SAGE-547, overcomes decreases in synaptic $GABA_A$ receptors occurring after prolonged seizure activity. SAGE-689 also has greater sedation potential than SAGE-547.

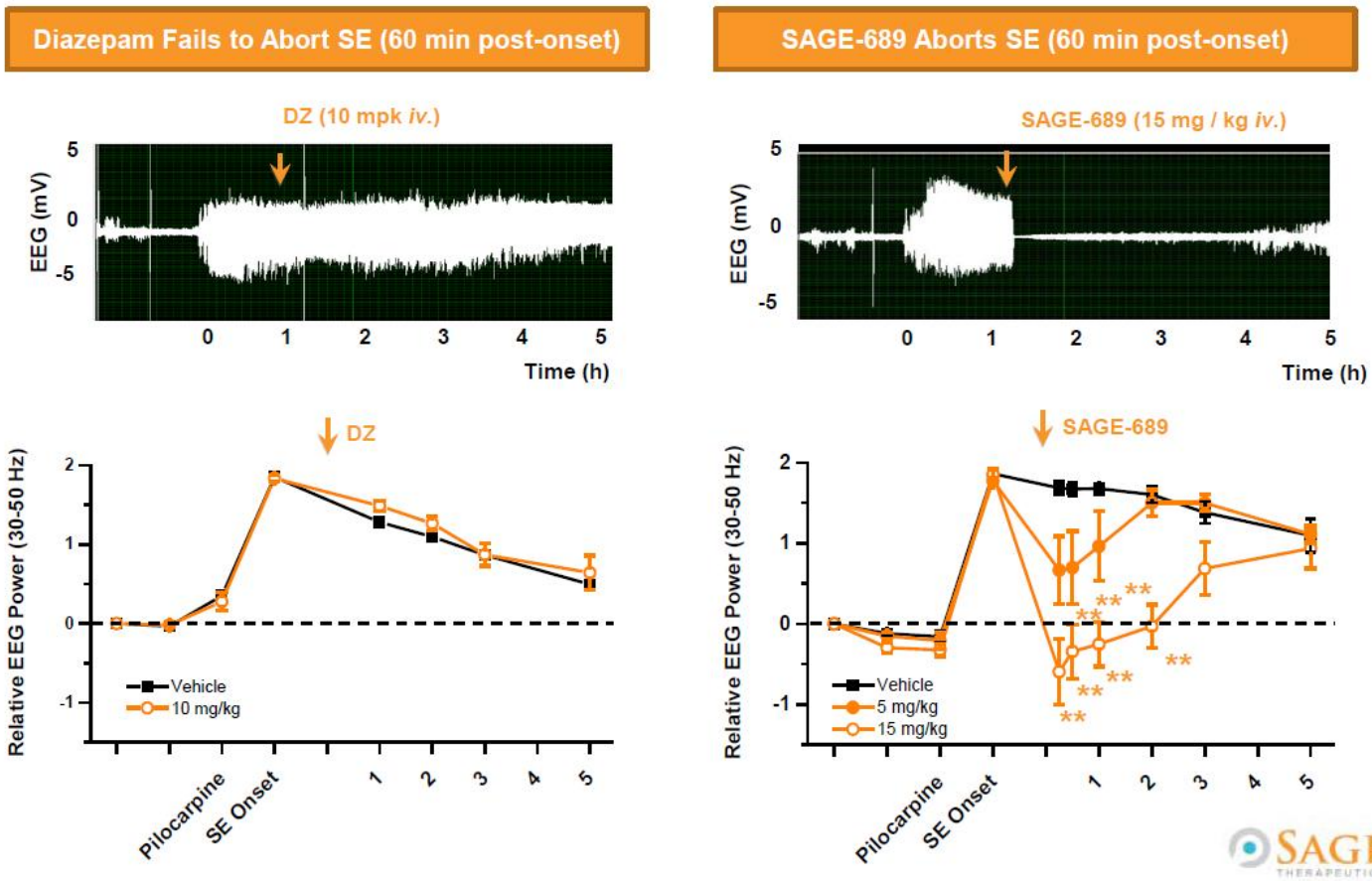
At present, only preclinical data are available for SAGE-689, but early studies show termination of seizures which are resistant to benzodiazapines. Utilizing a pilocarpine-induced seizure model, SAGE-689 was shown to abort status epilepticus at doses of 15 mg/kg, suggesting potential utility in status epilepticus (Figure 13).

Figure 12: SAGE-689 therapeutic index versus anesthesia



Source: SAGE Therapeutics, Company Presentations

Figure 13: Early data for SAGE-689 – pilocarpine induced seizure model



Source: SAGE Therapeutics, Company Presentations

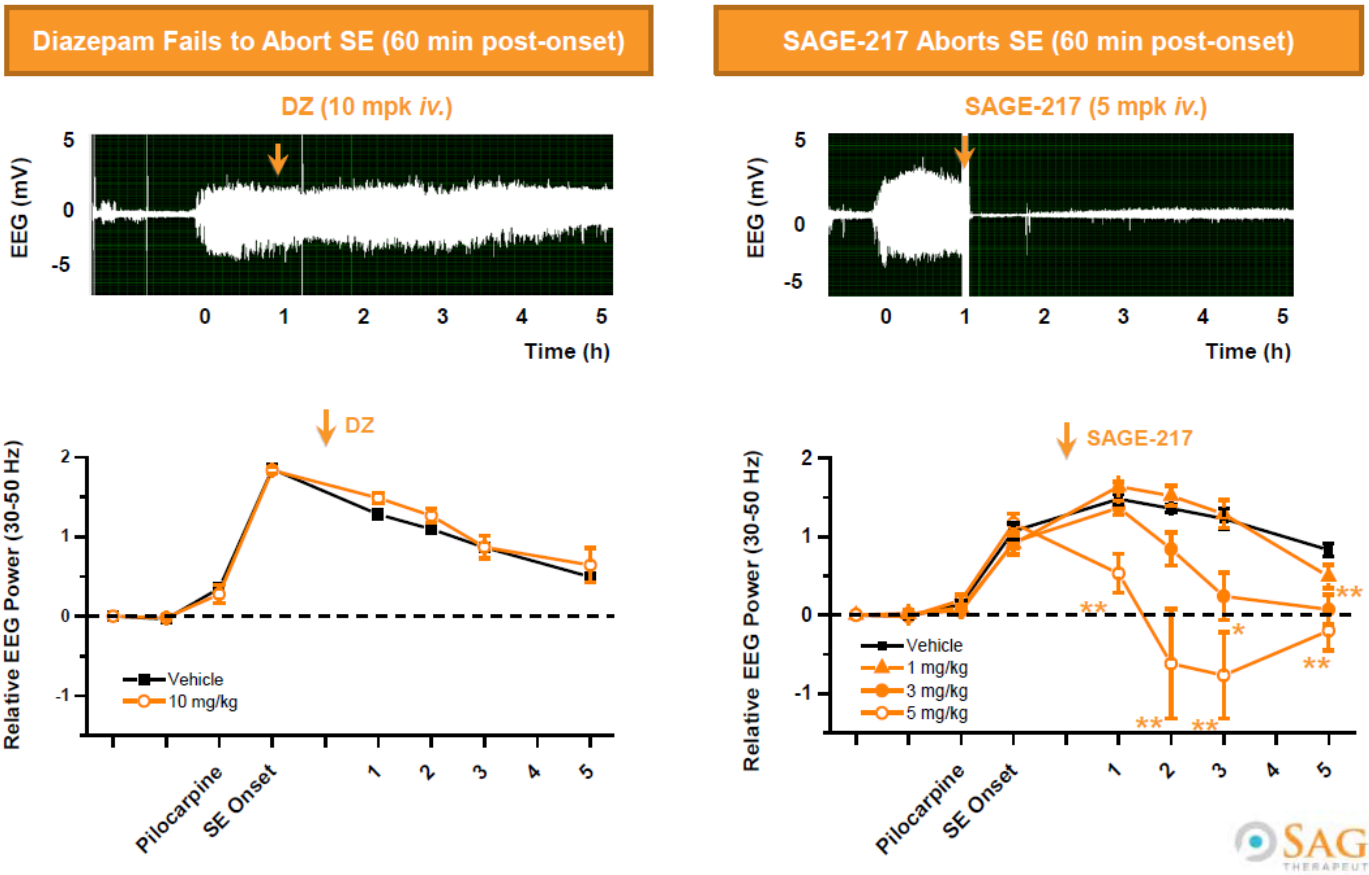
SAGE is currently conducting a Phase 1 proof-of-concept study for SAGE-689 in status epilepticus patients, testing safety, pK, pharmaco-EEG, and doses required for sedation/ anesthesia and burst suppression. The Phase 1a portion of the study will evaluate safety through general anesthesia and possible burst suppression, whereas the Phase 1b portion will involve dosing to burst suppression. SAGE will meet with FDA after Phase 1a data become available to discuss safety with the agency before moving to dosing to burst suppression in Phase 1b. The study will measure pK throughout, and SAGE-689 will be dosed as a 60-minute infusion in both the Phase 1a portion and Phase 1b portion of the study. Phase 1a data are expected by mid-2015.

SAGE-217 – ORAL MAINTENANCE FOR SEIZURE SUPPRESSION

SAGE's third asset is SAGE-217, also targeting the $GABA_A$ α4 extrasynaptic receptor, and is being developed as an oral new chemical entity for status epilepticus maintenance and seizure suppression in epilepsies. In addition, SAGE-217 is being formulated as an IV therapy for potential use in refractory status epilepticus. SAGE-217 has a long half-life designed for once daily dosing, which may minimize rapid fluctuations of drug in the blood.

Early data for SAGE-217 suggest the ability to abort status epilepticus in a pilocarpine-induced status epilepticus model at a dose of 5 mg/kg, which is encouraging and should facilitate additional clinical development. SAGE plans to file an IND for SAGE-217 in early 2015 and may also pursue development in other orphan diseases including Dravet Syndrome, Rett Syndrome, and Fragile X.

Figure 14: SAGE-217 activity pilocarpine induced status epilepticus model



Source: SAGE Therapeutics

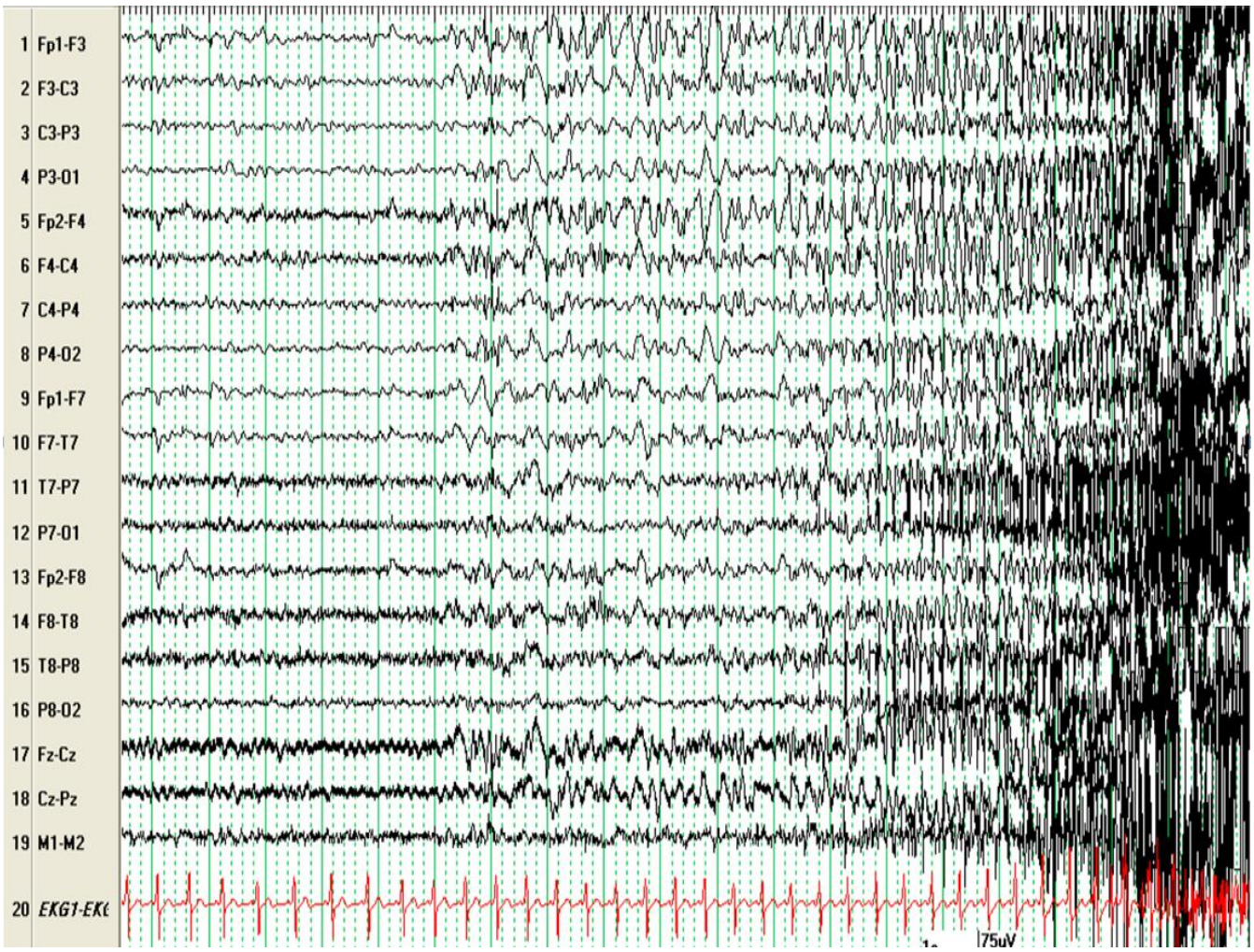
STATUS EPILEPTICUS – SERIOUS DISORDER, SUPER-REFRACTORY PATIENTS AT HIGH RISK

Status epilepticus is a very serious condition where the brain is in a constant state of seizure. The disease is generally defined as a seizure that is constant and lasting more than five minutes at a time, or seizures that recur without consciousness for five minutes or more. This condition is serious and carries a 20% mortality rate. Patients must seek immediate medical attention at a hospital, or neurological damage may occur.

Status epilepticus can be caused by many conditions, and only ~25% of patients have epilepsy. Causes include: stroke, hemorrhage, intoxicants, sudden withdrawal from a seizure medication, drinking alcohol with an anti-convulsant, gastroenteritis, insomnia, or sleep deprivation. Patients often present with symptoms including: focal or unilateral paresthesias or numbness, focal visual changes – usually characterized by flashing lights, focal visual obscuration or focal colorful hallucinations, olfactory or gustatory hallucinations, or atypical rising abdominal sensations.

Diagnosis is confirmed via glucose and electrolyte level testing (including calcium, magnesium), complete blood count, renal and liver function tests, toxicological screening and anticonvulsant drug levels, and arterial blood gas results. Additional tests that may be performed include EEG (Figure 15), blood cultures, and urinalysis and/or cerebrospinal fluid analysis. In addition, imaging studies including CT scanning and/or MRI of the brain or chest radiography may be performed.

Figure 15: Typical EEG for convulsive status epilepticus with generalized onset



Source: Vanderbilt Univ, Dept. Of Neurology

INTELLECTUAL PROPERTY

SAGE is building a meaningful patent estate for its three compounds, SAGE-547, SAGE-689, and SAGE-217. Importantly, SAGE has filed for composition of matter patents for SAGE-689 and SAGE-217, whereas SAGE-547 will not be eligible for composition of matter or NCE status. SAGE-547 has been granted orphan designation, however, which will protect the drug from generic competition for seven years after FDA approval. SAGE also plans to file for patent protection on all three assets outside the US.

Figure 16: Sage Therapeutics intellectual property

Drug	NCE?	Patent	Status	Type	Expiration	Comments
SAGE-547	no		filed	method of use	2033	Claims to compositions containing allopregnanolone and a cyclodextrin, used to treat CNS disorders such as traumatic brain injury and Status Epilepticus
SAGE-689	yes	7,781,421	issued	composition of matter	2027	Patent licensed from Washington University
			filed	composition of matter	2033	Composition patent in process for SAGE-689
			filed	method of use	2033	Use of SAGE-689 in anesthesia or treatment of GABA-related disorders
SAGE-217	yes		filed	composition of matter	2027	Patent licensed from Washington University
			filed	method of use	2032-2034	

Source: Canaccord Genuity, SAGE Therapeutics, SEC filings

FINANCIAL OVERVIEW

SAGE is a clinical stage biotechnology company that is not currently profitable and is unlikely to be profitable for the foreseeable future. The company currently has ~$150M in cash, including the recent IPO proceedings. SAGE has recently completed an initial public offering and will utilize the proceeds for Phase 1/2 development of SAGE-547 ($10M), IND-enabling activities and Phase 1 clinical development of SAGE-689 ($10M), as well as ~$7.0M to fund IND-enabling activities for SAGE-217.

SAGE currently has no debt outstanding, and we do not expect the company to issue debt until the company becomes profitable, which may not occur for many years. SAGE is currently conducting clinical studies in preparation for FDA submission and potential approval. As such, we expect the company to continue to burn cash and expect SAGE to raise additional funding through equity offerings. Therefore, shareholders should expect dilution, the level of which will vary depending on the stock price for the company. The company has approximately 27 million shares outstanding on a fully diluted basis, but we expect this number to increase as additional shares are issued going forward and also as options are exercised.

Figure 17: SAGE Therapeutics income statement

Revenues	2012A	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
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	**2012A**	**2013A**	**1Q14A**	**2Q14E**	**3Q14E**	**4Q14E**	**2014E**	**2015E**	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**
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	5,345	7,614	11,644	28,776	44,065	47,030	48,616	53,957	65,003	80,033
SAGE-547	125	3,918	1,174	1,761	2,906	5,375	11,216	16,912	17,250	12,075	8,453	7,607	6,847
SAGE-689	1,047	2,772	860	869	1,303	1,954	4,986	10,315	11,346	15,317	20,678	27,915	37,686
SAGE-217	-	1,129	667	1,001	1,401	1,961	5,029	7,398	8,878	11,541	15,003	19,504	25,355
other r&d	3,495	3,388	273	276	278	281	1,108	1,153	1,269	1,396	1,535	1,689	1,858
Unallocated expenses	2,562	3,150	1,199	1,439	1,727	2,072	6,436	8,287	8,287	8,287	8,287	8,287	8,287
Personnel related expenses	2,116	2,718	1,116	1,127	1,138	1,150	4,531	4,715	1,208	4,763	1,221	4,810	1,233
Other expenses	446	432	83	84	85	86	337	351	90	354	91	358	92
General and administrative	2,402	3,922	1,617	1,633	1,650	1,666	6,566	6,832	6,940	7,010	32,052	34,870	37,965
Personnel related	899	1,764	627	633	640	646	2,546	2,649	2,715	2,743	27,743	30,517	33,569
Professional fees	929	1,253	737	744	752	759	2,993	3,114	3,145	3,177	3,208	3,240	3,273
Facilities	266	364	98	99	100	101	398	414	418	422	427	431	435
Other	308	541	155	157	158	160	629	655	661	668	675	682	688
Total Operating Expense	9,631	18,279	5,790	6,978	9,264	13,310	35,342	50,898	53,970	55,626	86,009	99,873	117,998
EBITDA													
Operating income	(9,631)	(18,279)	(5,790)	(6,978)	(9,264)	(13,310)	(35,342)	(50,898)	(53,970)	(55,626)	(4,429)	211,544	461,090
Interest (expense) income, net	-	1	-	-	-	-	-	-	-	-	-	-	-
Other income (expense), net	(1)	(3)	-	-	-	-	-	-	-	-	-	-	-
Pre-tax income (GAAP)	(9,632)	(18,281)	(5,790)	(6,978)	(9,264)	(13,310)	(35,342)	(50,898)	(53,970)	(55,626)	(4,429)	211,544	461,090
Pre-tax income (non-GAAP)													
Taxes (GAAP)		-	-	-	-	-	-	-	-	-	-	78,271	170,603
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Accretion of redeemable convertible preferred	(4)	(7)	(326)										
Net Income (GAAP)	**(9,637)**	**(18,288)**	**(6,116)**	**(6,978)**	**(9,264)**	**(13,310)**	**(35,668)**	**(50,898)**	**(53,970)**	**(55,626)**	**(4,429)**	**133,273**	**290,487**
GAAP EPS (diluted)	($8.62)	($12.26)	($3.70)	($0.26)	($0.34)	($0.48)	($1.45)	($1.64)	($1.68)	($1.58)	($0.11)	$3.12	$6.18

Source: Company reports, Canaccord Genuity estimates

Figure 18: SAGE Therapeutics balance sheet

Balance Sheet												
(000's) [FY - DEC]	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
ASSETS												
Current assets:												
Cash and cash equivalents	$ 8,066	$ 55,425	$ 160,426	$ 150,966	$ 137,442	$ 137,442	$ 136,445	$ 132,788	$ 77,646	$ 73,692	$ 207,429	$ 498,369
Prepaid expenses and other current assets	341	1,235	2,981	3,130	3,286	3,286	4,194	4,624	4,855	5,098	5,353	5,621
Total current assets	**8,407**	**56,660**	**163,407**	**154,096**	**140,729**	**140,729**	**140,639**	**137,412**	**82,502**	**78,790**	**212,782**	**503,990**
Property and equipment, net	86	78	112	118	124	124	158	174	183	192	201	211
Restricted cash	39	39	-	-	-	-	-	-	-	-	-	-
Total assets	**$ 8,532**	**$ 56,777**	**$ 163,519**	**$ 154,214**	**$ 140,852**	**$ 140,852**	**$ 140,797**	**$ 137,586**	**$ 82,684**	**$ 78,982**	**$ 212,983**	**$ 504,201**
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT												
Current liabilities:												
Accounts payable	$ 1,988	$ 1,626	$ 521	$ 547	$ 575	$ 575	$ 734	$ 809	$ 849	$ 892	$ 936	$ 983
Accrued expenses	327	1,462	4,769	5,008	5,258	5,008	6,391	7,399	7,769	8,157	8,565	8,993
Total current liabilities	**2,315**	**3,088**	**5,291**	**5,555**	**5,833**	**5,833**	**7,444**	**8,207**	**8,618**	**9,049**	**9,501**	**9,976**
Other liabilities	44	36	298	298	298	298	298					
Total liabilities	**$ 2,359**	**$ 3,124**	**$ 5,589**	**$ 5,853**	**$ 6,131**	**$ 6,131**	**$ 7,742**	**$ 8,207**	**$ 8,618**	**$ 9,049**	**$ 9,501**	**$ 9,976**
Commitments and contingencies:												
Redeemable convertible preferred stock	37,709	-				-	-					
Total stockholders' equity (deficit)	(31,536)	53,653	157,931	148,361	134,721	134,721	133,055	129,379	74,067	69,933	203,482	494,225
Total liabilities, convertible preferred stock and												
Total liabilities and equity	$ 8,532	$ 56,777	$ 163,519	$ 154,214	$ 140,852	$ 140,852	$ 140,797	$ 137,586	$ 82,684	$ 78,982	$ 212,983	$ 504,201

Source: Company reports, Canaccord Genuity estimates

Figure 19: SAGE Therapeutics statement of cash flows

Statements of Cash Flows												
(000's) [FY - DEC]	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
CASH FLOWS USED IN OPERATING ACTIVITIES:												
Net loss	(18,281)	(5,790)	(6,978)	(9,264)	(13,310)	(35,342)	(50,898)	(53,970)	(55,626)	(4,429)	133,273	290,487
Adjustments to reconcile net loss to net cash used in operating activities:												
Stock-based compensation expense	61	160	160	160	160	640	640	640	640	640	640	640
Non-cash interest expense	-											
Licensing or consultant fees paid in common stock	64	127										
Depreciation and amortization	47	11	11	11	11	44	44	44	44	44	44	44
Prepaid expenses and other current assets	(317)	(52)	(1,746)	(149)	(156)	(2,103)	(908)	(430)	(231)	(243)	(255)	(268)
Accounts payable	674	(471)	(1,105)	26	27	(1,522)	159	75	40	42	45	47
Accrued expenses and other current liabilities	236	399	(3,307)	(238)	(250)	(3,397)	-					
Cash flow from operations	**(17,516)**	**(5,616)**	**(12,965)**	**(9,454)**	**(13,518)**	**(41,553)**	**(50,963)**	**(53,641)**	**(55,133)**	**(3,945)**	**133,746**	**290,950**
CASH FLOWS PROVIDED BY INVESTING ACTIVITIES:												
Purchases of property and equipment	(3)	(3)	(34)	(6)	(6)	(49)	(34)	(16)	(9)	(9)	(10)	(10)
Restricted cash	-	-				-	-					
Cash flow from investing	**(3)**	**(3)**	**(34)**	**(6)**	**(6)**	**(49)**	**(34)**	**(16)**	**(9)**	**(9)**	**(10)**	**(10)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:												
Proceeds from convertible notes payable	-	-				-	-					
Proceeds from issuance of Series A preferred stock, net of issua	22,732		50,000			50,000	-					
Proceeds from issuance of Series B preferred stock, net of issua	-	14,995				14,995	-					
Proceeds from issuance of Series C preferred stock, net of issua	-	37,981				37,981	-					
Proceeds from the issuance of common stock and restricted stoc	51	2	68,000			68,002	50,000	50,000				
Cash flow from financing	**22,783**	**52,978**	**118,000**	**-**	**-**	**170,978**	**50,000**	**50,000**	**-**	**-**	**-**	**-**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALE	5,264	47,359	105,001	(9,460)	(13,524)	129,376	(997)	(3,657)	(55,141)	(3,954)	133,737	290,940
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,802	8,066	55,425	160,426	150,966	8,066	137,442	136,445	132,788	77,646	73,692	207,429
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**8,066**	**55,425**	**160,426**	**150,966**	**137,442**	**137,442**	**136,445**	**132,788**	**77,646**	**73,692**	**207,429**	**498,369**

Source: Company reports, Canaccord Genuity estimates

APPENDIX: IMPORTANT DISCLOSURES

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(as of 3 July 2014)

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Speculative Buy	49	5.0%	55.1%
Hold	290	29.5%	13.1%
Sell	41	4.2%	7.3%
	984	100.0%	

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

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