SAGE Therapeutics, Inc. (SAGE)

Q4 EPS Postview, Looking to SAGE-547 Pivotal Trial Start by Mid-15

Buy

Price Target: $67.00
Prior: $67.00

Price (Feb. 26, 2015)	$42.99
52-Wk Range	$44.73-$25.86
Market Cap ($M)	$1,109
ADTV	149,711
Shares Out (M)	25.8
Short Interest Ratio/% Of Float	9.1%
TR to Target	55.9%

Cash Per Share	$4.12
Total Debt	$0.0
Cash And Equivalents ($M)	$127.8

	2014E	2015E		2016E	
		Curr.	Prior	Curr.	Prior
Revenue ($M)					
FY	0	0	0	0	0
EPS Adjusted					
FY	(1.67)A	(2.52)	(2.28)	(2.86)	--
P/E	NM	NM		NM	
Consensus Rev					
FY	0	0	0	0	0
Consensus EPS Adjusted					
FY	(2.51)A	(2.09)	(2.02)	(2.44)	(2.66)
FYE Dec					

What's Incremental

SAGE reported Q4 net loss of $12.4M, compared to STRH at $11.6 and consensus of $11M. The company ended the quarter with $127.8M in cash, which we believe is sufficient to fund operations into 2016. The key catalyst for SAGE is the outcome of its expected interaction with the FDA in Q1/15, to guide the design of a pivotal trial of lead drug SAGE-547 for SRSE. Management guided that the study duration could range from 1-2 years, we conservatively model the higher end of this range. Shorter completion timelines would be upside to our estimates.

Q4 EPS updates highlights SAGE-547 on track to begin pivotal testing in SRSE by mid-15. We spoke with management, and the timeline for the SAGE key catalyst remains unchanged: a planned End-of-Phase II meeting with the FDA on track for Q1, to inform the design of a pivotal study of SAGE-547 for super refractory status epilepticus (SRSE). SAGE expects final results from an ongoing Phase I/II study of 547 in SRSE to report out by mid-2015. We believe these data could be potentially presented as a Late Breaker abstract at the American Academy of Neurology (AAN) meeting, Apr 18-25, Washington DC) or at the London-Innsbruck Colloquium on Status Epilepticus (Apr 9-11, London). Management guidance for a pivotal study of 547 for SRSE is unchanged: the trial is expected to begin by mid-2015, to enroll 100-200 patients and with a duration of 1-2 years. Recall that the design of this trial could be either randomized controlled or entail a single arm and use historical data as control. The second scenario would be spurred by hospital review boards looking at ~71% response rates in the Phase I/II trial, which appear compelling in light of 22-43% historical response rates in SRSE.

SAGE is making good progress with the remainder of pipeline programs. The company reiterated the timing of the expected 2015 catalysts: 1) readout of two Phase IIa studies of SAGE-547 (used as a probe molecule) for essential tremor and post-partum depression by mid-2015; 2) launch of a Phase I study of follow-on oral molecule SAGE-217 in orphan epilepsies in late-2015; and 3) launch of a Phase I trial of follow-on molecule SAGE-689 as adjunctive i.v. second-line therapy for refractory status epilepticus.

Limited changes to model following Q4 results: Based on the current OpEx trajectory and our discussions with management, we are increaseing our FY15 R&D forecast to $46.8M from $45M previously, and our SG&A forecast to $18.5M from our previous $14.3M estimate. Our FY15 GAAP EPS

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estimate is now $(252) versus $(2.28) previously. Our out-year estimates are unchanged, and we continue to conservatively forecast a SAGE-547 pivotal trial duration at the higher end of management guidance of 1-2 years. A shorter study duration could translate into earlier than expected U.S. SAGE-547 approval for SRSE, and upside to our estimates of $0M revenue in FY17.

Figure 1: Q4/14 Variance Table

($thousands, except per share data)

	Dec Q4 2014A	Dec Q4 2014E	Variance A-E	Variance %	Y/Y %	Q/Q %
Revenue						
	-	-	-	N/A	N/A	N/A
Total Revenue	**$ -**	**$ -**	**$ -**	**N/A**	**N/A**	**N/A**
Operating expense			-			
R&D (GAAP)	8,945	8,005	940	11%	-8%	36%
SG&A (GAAP)	3,417	3,215	202	6%	-27%	19%
Stock-based compensation	-	-	-		-100%	
Other	-	-	-			
Total operating expense	12,362	11,220	1,142	9%	-14%	31%
Operating income (loss)	(12,362)	(11,220)	(1,142)	9%	52%	31%
Interest Income (expense), net	4	4	0	2%	-50%	33%
Other income (expense), net	-	-	-			
Other (expense) income, net	1	4	(3)	-293%	-97%	-50%
Income Before Income Taxes	**(12,361)**	**(11,216)**	(1,145)	9%	53%	31%
Income Tax Provision	-	-	-			
Foreign currency translation adjustment	-	-	-			
Unrealized gains (losses) on marketable securities	-	-	-			
Total other comprehensive income (loss)	-	-	-			
Comprehensive loss	**(12,361)**	**(11,216)**	(1,145)	9%	53%	31%
Accretionof redeemable convertible preferred stock	-	(391)	391			N/A
Gain on extinguishment of convertible preferred stock	-	-	-			
Net loss applicable to common shareholders	**$ (12,361)**	**$ (11,607)**	(754)	6%	53%	25%
GAAP EPS (diluted)	**$ (0.48)**	**$ (0.45)**	(0.03)	7%	42%	-4%
Weighted shares outstanding basic and diluted - GAAP	25,608	25,792	- (184)	-1%	8%	31%

Source: STRH analysis and Company reports

Figure 2: Upcoming Expected Milestones

Product	Timing	Indication	Event
SAGE-547	Q1 2015	Super refractory status epilepticus (IV)	End-of-Phase II (EOP2) meeting with the FDA
SAGE-547	Q1 2015	Super refractory status epilepticus (IV)	Announce EOP2 meeting outcome
SAGE-547	**By mid-2015**	**Super refractory status epilepticus (IV)**	**Announce final data from a Phase I/II trial**
SAGE-547	**By mid-2015**	**Post-partum Depression**	**Phase II topline data**
SAGE-547	**By mid-2015**	**Essential Tremor**	**Phase II topline data**
SAGE-547	By Mid-2015	Super refractory status epilepticus (IV)	Initiate pivotal trial
SAGE-689	Late-2015	Adjunctive Status Epilepticus (IV)	Initiate Phase I testing
SAGE-217	Late-2015	Orphan Genetic Seizure Disorders (oral)	Initiate Phase I testing
NMDA modulator	Late-2015	Undisclosed orphan indication	Announce next program

Source: STRH analysis and Company reports

Sage Therapeutics

(NASDAQ: SAGE)

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Consolidated Income Statement

($thousands, except per share data)	FY 2012A	FY 2013A	FY 2014A	Mar Q1 2015A	Jun Q2 2015A	Sep Q3 2015E	Dec Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E
Revenue																			
SAGE-547	$ -	$ -	$ -	-	-	-	-	$ -	$ -	$ -	$ 63,810	$ 332,738	$ 545,591	$ 809,859	$ 951,793	$ 1,130,111	$ 1,394,818	$ 1,564,672	$ 1,680,410
Total Revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 332,738	$ 545,591	$ 809,859	$ 951,793	$ 1,130,111	$ 1,394,818	$ 1,564,672	$ 1,680,410
COGS	-	-	-	-	-	-	-	-	-	-	5,105	36,601	60,015	89,084	95,179	113,011	139,482	156,467	168,041
Gross profit	-	-	-	-	-	-	-	-	-	-	58,705	296,137	485,576	720,774	856,614	1,017,100	1,255,336	1,408,205	1,512,369
Operating expense																			
R&D (GAAP)	7,229	14,357	24,100	9,542	10,559	12,155	14,546	46,802	60,221	70,224	80,334	90,211	100,260	110,299	120,317	130,877	140,903	150,756	160,901
SG&A (GAAP)	2,402	3,922	9,710	3,812	4,044	5,157	5,544	18,557	23,556	48,910	74,002	79,043	84,056	89,054	94,829	99,901	104,055	109,007	114,018
Total operating expense	9,631	18,279	33,810	13,354	14,603	17,312	20,090	65,359	83,777	119,134	154,336	169,254	184,316	199,353	215,146	230,778	244,958	259,763	274,919
Operating income (loss)	**(9,631)**	**(18,279)**	**(33,810)**	**(13,354)**	**(14,603)**	**(17,312)**	**(20,090)**	**(65,359)**	**(83,777)**	**(119,134)**	**(95,631)**	**126,883**	**301,260**	**521,421**	**641,468**	**786,322**	**1,010,378**	**1,148,442**	**1,237,450**
Interest Income (expense), net	-	1	8	4	4	5	4	17	34	54	58	91	212	426	746	1,203	1,828	2,558	3,404
Other income (expense), net	(1)	(3)	(9)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Other Income	(1)	(2)	(1)	4	4	5	4	17	34	54	58	91	212	426	746	1,203	1,828	2,558	3,404
Income before income taxes	(9,632)	(18,281)	(33,811)	(13,350)	(14,599)	(17,307)	(20,086)	(65,342)	(83,743)	(119,080)	(95,573)	126,974	301,472	521,848	642,214	787,525	1,012,206	1,151,000	1,240,854
Provision for income taxes	-	-	-	-	-	-	-	-	-	-	-	12,697	30,147	78,277	192,664	236,257	303,662	345,300	372,256
Net gain (loss)	**(9,632)**	**(18,281)**	**(33,811)**	**(13,350)**	**(14,599)**	**(17,307)**	**(20,086)**	**(65,342)**	**(83,743)**	**(119,080)**	**(95,573)**	**114,276**	**271,325**	**443,570**	**449,550**	**551,267**	**708,544**	**805,700**	**868,598**
Accretion of redeemable convertible preferred stock	(4)	(7)	(2,294)																
Net gain (loss) applicable to common shareholders	$ (9,636)	$ (18,288)	$ (36,105)	$ (13,350)	$ (14,599)	$ (17,307)	$ (20,086)	$ (65,342)	$ (83,743)	$ (119,080)	$ (95,573)	$ 114,276	$ 271,325	$ 443,570	$ 449,550	$ 551,267	$ 708,544	$ 805,700	$ 868,598
GAAP EPS (diluted)	$ (2.74)	$ (12.26)	$ (1.67)	$ (0.52)	$ (0.56)	$ (0.67)	$ (0.77)	$ (2.52)	$ (2.86)	$ (3.92)	$ (2.92)	$ 3.16	$ 7.15	$ 11.13	$ 10.75	$ 12.55	$ 15.36	$ 16.64	$ 17.08
Weighted shares outstanding basic and diluted (k)	3,522,607	1,492	21,574	25,736	25,865	25,994	26,124	25,930	29,242	30,368	32,719	36,139	37,946	39,843	41,835	43,927	46,123	48,429	50,851
Margin Analysis:																			
Cost of product sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	8%	11%	11%	11%	10%	10%	10%	10%	10%
Product gross margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	92%	89%	89%	89%	90%	90%	90%	90%	90%
R&D (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	126%	27%	18%	14%	13%	12%	10%	10%	10%
SG&A (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	116%	24%	15%	11%	10%	9%	7%	7%	7%
Stock-based compensation expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total operating expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	242%	51%	34%	25%	23%	20%	18%	17%	16%
Operating margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-150%	38%	55%	64%	67%	70%	72%	73%	74%
Income tax provision	N/A	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	10%	15%	30%	30%	30%	30%	30%
Net margin (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-150%	34%	50%	55%	47%	49%	51%	51%	52%
Y/Y change:																			
Total revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	521%	164%	148%	118%	119%	123%	112%	107%
SAGE-547 revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	521%	164%	148%	118%	119%	123%	112%	107%
R&D (GAAP)	N/A	99%	68%	129%	141%	84%	63%	94%	29%	17%	14%	12%	11%	10%	9%	9%	8%	7%	7%
SG&A (GAAP)	N/A	63%	148%	136%	124%	80%	62%	91%	27%	108%	51%	7%	6%	6%	6%	5%	4%	5%	5%
Stock-based compensation expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total operating expense	N/A	90%	85%	131%	136%	83%	63%	93%	28%	42%	30%	10%	9%	8%	8%	7%	6%	6%	6%
Operating income	N/A	90%	85%	131%	136%	83%	63%	93%	28%	42%	-20%	-233%	137%	73%	23%	23%	28%	14%	8%
Net income (GAAP)	N/A	90%	97%	118%	88%	76%	62%	81%	28%	42%	-20%	-220%	137%	63%	1%	23%	29%	14%	8%
GAAP EPS (diluted)	N/A	348%	-86%	-56%	-88%	32%	59%	-51%	-14%	-37%	26%	208%	-126%	N/A	-3%	17%	22%	8%	3%
Shares outstanding - GAAP	N/A	-100%	1346%	394%	1421%	33%	2%	20%	13%	4%	8%	10%	5%	5%	5%	5%	5%	5%	5%

Source: STRH Research, Company Reports

Revision Table

($thousands, except per share data)	FY15E		FY16E		FY17E		FY18E		FY19E		FY20E	
	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior
Revenue												
SAGE-547	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 63,810	$ 332,738	$ 332,738	$ 545,591	$ 545,591
% growth (QoQ or YoY)	-	-	-	-	-	-	-	-	4.2	4.2	0.6	0.6
SAGE-689	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
% growth (QoQ or YoY)	-	-	-	-	-	-	-	-	-	-	-	-
SAGE-217	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
% growth (QoQ or YoY)	-	-	-	-	-	-	-	-	-	-	-	-
Undisclosed NMDA Program	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
% growth (QoQ or YoY)	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ 63,810	$ 63,810	$ 332,738	$ 332,738	$ 545,591	$ 545,591
COGS	-	-	-	-	-	-	5,105	5,105	36,601	36,601	60,015	60,015
Gross profit	-	-	-	-	-	-	58,705	58,705	296,137	296,137	485,576	485,576
Operating expense												
R&D (GAAP)	46,802	45,302	60,221	60,221	70,224	70,224	80,334	80,334	90,211	90,211	100,260	100,260
SG&A (GAAP)	18,557	14,343	23,556	23,556	48,910	48,910	74,002	74,002	79,043	79,043	84,056	84,056
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	-	-
Total operating expense	65,359	59,645	83,777	83,777	119,134	119,134	154,336	154,336	169,254	169,254	184,316	184,316
Operating income (loss)	**(65,359)**	**(59,645)**	**(83,777)**	**(83,777)**	**(119,134)**	**(119,134)**	**(95,631)**	**(95,631)**	**126,883**	**126,883**	**301,260**	**301,260**
Interest Income (expense), net	17	21	34	35	54	56	58	60	91	93	212	215
Other income (expense), net	-	-	-	-	-	-	-	-	-	-	-	-
Other (expense) income, net	17	21	34	35	54	56	58	60	91	93	212	215
Income before income taxes	(65,342)	(59,624)	(83,743)	(83,742)	(119,080)	(119,078)	(95,573)	(95,571)	126,974	126,976	301,472	301,475
Provision for income taxes	-	-	-	-	-	-	-	-	12,697	12,698	30,147	30,147
Net gain (loss)	(65,342)	(59,624)	(83,743)	(83,742)	(119,080)	(119,078)	(95,573)	(95,571)	114,276	114,278	271,325	271,327
Accretion of redeemable convertible preferred stock	-	-	-	-	-	-	-	-	-	-	-	-
Net loss applicable to common shareholders	$ (65,342)	$ (59,624)	$ (83,743)	$ (83,742)	$ (119,080)	$ (119,078)	$ (95,573)	$ (95,571)	$ 114,276	$ 114,278	$ 271,325	$ 271,327
GAAP EPS (diluted)	$ (2.52)	$ (2.28)	$ (2.86)	$ (2.85)	$ (3.92)	$ (3.90)	$ (2.92)	$ (2.90)	$ 3.16	$ 3.14	$ 7.15	$ 7.11
Weighted shares outstanding basic and diluted	25,930	26,116	29,242	29,432	30,368	30,559	32,719	32,921	36,139	36,350	37,946	38,167

Source: STRH Research, Company Reports

Company Description

SAGE Therapeutics, Inc. is a biopharmaceutical company focused on developing and commercializing novel medicines to treat life threatening, rare central nervous system disorders. Its lead program SAGE-547 is in clinical development for super-refractory status epilepticus and is the first of several compounds the company is developing in its portfolio of potential seizure medicines. The company's robust chemistry platform has generated multiple new compounds that target the GABA-A and NMDA receptors, which are well-characterized with regard to their role in many psychiatric and neurological disorders.

Investment Thesis

SAGE is positioning itself as a premier orphan play, focused on central nervous system (CNS) diseases of high unmet need, with well-defined molecular characteristics and likely short drug development timelines. SAGE is one of the few players in the CNS space, a field with significant unmet need – that has been historically difficult to tackle in drug development. The company recently went public, with the key strategy to use its broad platform (chemical modulators of brain molecules) to focus on drug development for CNS indications that are: 1) well-defined from a molecular perspective, and 2) have short drug development timelines (small numbers of patients, short clinical trial duration). SAGE's lead drug candidate is SAGE-547, a modulator of the neural gamma-amino butyric acid (GABA) receptor. SAGE-547 is about to enter pivotal testing in mid-2015 for super-refractory status epilepticus, a rare type of epilepsy characterized by persistent seizures (>24 hours), in spite of treatment with multiple rounds of anesthetics. The company has two second generation molecules in the wings (SAGE-217 and SAGE-689) expected to enter the clinic in late-2015, as well as a platform of early stage modulators (N-Methyl-D-aspartic acid receptor, NMDA) of cellular brain function, slated to expand the epilepsy/CNS orphan disease franchise.

Valuation and Risks

We arrive at our price target of $67 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes $53.49/share to SAGE-547 U.S. sales, $8.76 to SAGE-547 E.U. sales, $0.62 to SAGE-547 ROW sales, and $4.38/share to cash. We assign SAGE-547 in a probability of success of 58% in the U.S., 25% in the E.U., and 25% in ROW. We assume a discount rate of 12% and a 1% terminal growth rate to SAGE-547 in the U.S. and the E.U., and no terminal value for SAGE-547 in ROW.

Risks:

- **Clinical Risk:** SAGE-547 may fail to repeat its 71-78% response rate from Phase II trials and eIND use in a pivotal trial. It is possible that both the Phase II and eIND patients had a higher chance of recovering from SRSE than the ~30% chance quoted by SAGE, and of the 30-50% chance quoted by our physician consultants. This could be due to the inclusion/exclusion criteria used in Phase II, or another reason altogether. Although preclinical rationale for SAGE-547 is suggestive that the compound could have utility in ET and PPD, the benefit in animals may not translate well in humans. Finally, although they have similar putative mechanisms of action, there is some chance that proof-of-concept for SAGE-547 does not read through to other GABA modulators SAGE-689 and SAGE-217.

- **Regulatory risk:** The FDA may require more rigorous clinical trials than we anticipate. We believe that SAGE's expected Phase III endpoint of being seizure-free after the patient is weaned from both general anesthesia and SAGE-547 should be appropriate. However, the FDA may ask for a randomized controlled study, which may be difficult to set up given the variability in standard of care among different treatment centers. Longer term follow-up could be required, for example an endpoint such as % of patients who are seizure free 1 month after wean. We expect clarity on this endpoint in Q1 2015, when SAGE communicates the results of their end-of-Phase II meeting with FDA.

- **Commercial risk:** SAGE plans to target the relatively small number of ICUs (~900 hospitals in the U.S.) and epilepsy treatment centers (~200 in the U.S.), where SRSE patients are treated. E.U. has

a comparable number of centers. The remains a commercial risk (albeit low) that SAGE is unable to effectively reach these patients.

- **Competitive Risk:** Although we are not aware of any significant competitive drugs in development for status epilepticus (SE), Marinus Pharmaceuticals (MRNS) is developing ganaxolone, a similar GABA-receptor targeted agent (although restricted to hitting the synaptic receptors), for the treatment of other forms of epilepsy and Fragile X syndrome. Although ganaxolone is unlikely to be approved for SE without clinical trials in that population, if the drug does become available it could be used off-label.
- **Financial risk:** Given the expenses associated with conducting clinical trials and launch of the product, we anticipate that SAGE may have to issue additional equity through follow-on offerings

Companies Mentioned in This Note

SAGE Therapeutics, Inc. (SAGE, $42.99, Buy)

Analyst Certification

I, Salveen Richter , hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

Required Disclosures

SunTrust Robinson Humphrey, Inc. makes a market in the following companies at the time of this report: SAGE, SAGE-US

Analyst compensation is based upon stock price performance, quality of analysis, communication skills, and the overall revenue and profitability of the firm, including investment banking revenue.

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STRH Ratings System for Equity Securities

3 designations based on total returns* within a 12-month period**

- **Buy** – total return ≥ 15% (10% for low-Beta securities)***
- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
- **Neutral** – total return is within the bounds above
- **NR** – NOT RATED, STRH does not provide equity research coverage
- **CS** – Coverage Suspended

*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
***Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

SunTrust Robinson Humphrey ratings distribution (as of 02/27/2015):

Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	281	52.04%	Buy	99	35.23%
Neutral	248	45.93%	Neutral	43	17.34%
Sell/Reduce	11	2.04%	Sell/Reduce	2	18.18%

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