

## SAGE Therapeutics

# Positive early metrics for Zurzuva launch but clarity on long-term oppy needed

Reiterate Rating: NEUTRAL | PO: 29.00 USD | Price: 23.02 USD

## ~120 Zurzuva scripts written in first days of launch

Sage Therapeutics (SAGE) reported 4Q revenues of Zurzuva of \$0.8mn (50% profit share with partner Biogen). The company highlighted 4Q revs represent only 10 days since the launch in mid-December. Mgmt commented ~120 scripts were written in December with 70% being shipped and delivered between December and early January, and they continue to see growing demand in 1Q. Mgmt noted initial scripts are coming from OBGYNs and psychiatrists, with a small percent coming from PCPs. They noted payor coverage has been positive so far with no significant headwinds, and they continue to work on optimizing access with commercial coverage increasing in 1H followed by Medicaid in 2H. Mgmt noted they remain focused on increasing awareness of PPD treatment and diagnosis. We are encouraged by positive early metrics for the Zurzuva launch but continue to look for visibility on long-term uptake. We await additional visibility on payor dynamics and potential increase in diagnosis and treatment rates in PPD to inform the commercial opportunity for Zurzuva. We reiterate our Neutral rating with new \$29 PO (prev. \$30).

## Several readouts from dalza' and '324 in 2024

On dalzanemdor (SAGE-718), mgmt highlighted cognitive impairment (CI) associated with Huntington's disease (HD) as the lead indication. They expect to report ph 2 data from the SURVEYOR study in mid-24, which aims to provide supportive evidence in CI in HD and complement the ph 2 DIMENSION study. However, they noted it is not powered to show stat sig benefit over placebo. DIMENSION, a double-blind, placebo-controlled trial, is evaluating the efficacy of dalza' over 3 months in 178 pts and is expected to readout in late-24. Additional readouts for dalza' include the ph 2 PRECEDENT study in mild CI in Parkinson's in early-24 and the ph 2 LIGHTWAVE study in mild CI and mild dementia in Alzheimer's in late-24. On SAGE-324, the company reiterated that topline data for the ph 2 KINECT 2 study in essential tremor (ET) is expected in mid-24. The company noted the goal of KINECT 2 is to identify the optimal dose for chronic treatment of ET as well as potential benefit activities of daily living.

## Model changes

In our DCF-based model, we update for 4Q results, cash and share count. We also slightly increase our peak penetration for Zurzuva in PPD to 13% (prev. 10%) based on initial positive launch metrics. We lower our Zulresso estimates based on commentary from the company on expected decreasing revenues after the approval of Zurzuva and increase our pipeline value to \$850mn given several updates from dalza' and 324 expected in 2024. These changes result in our new \$29 PO (prev. \$30).

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(8.98)	(9.05)	(6.46)	(3.99)	(1.29)
EPS Change (YoY)	-15.1%	-0.8%	28.6%	38.2%	67.7%
Consensus EPS (Bloomberg)			(6.13)	(5.46)	(3.02)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-33.3%	-39.1%	-26.8%	-15.4%	-9.8%

\* For full definitions of *IQmethod*<sup>SM</sup> measures, see page 5.

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14 February 2024

### Equity

#### Key Changes

(US\$)	Previous	Current
Price Obj.	30.00	29.00
2024E Rev (m)	83.4	22.3
2025E Rev (m)	98.7	107.3
2026E Rev (m)	NA	139.4
2024E EPS	-5.11	-6.46
2025E EPS	-3.82	-3.99
2026E EPS	NA	-1.29

**Tazeen Ahmad**  
Research Analyst  
BofAS  
+1 646 855 4236  
[tazeen.ahmad@bofa.com](mailto:tazeen.ahmad@bofa.com)

**Daniel Giraldo**  
Research Analyst  
BofAS  
[daniel.giraldoperez@bofa.com](mailto:daniel.giraldoperez@bofa.com)

**Jeremiah Lorentz**  
Research Analyst  
BofAS  
[jeremiah.lorentz@bofa.com](mailto:jeremiah.lorentz@bofa.com)

### Stock Data

Price	23.02 USD
Price Objective	29.00 USD
Date Established	14-Feb-2024
Investment Opinion	C-2-9
52-Week Range	16.52 USD - 59.99 USD
Mkt Val (mn) / Shares Out (mn)	1,384 USD / 60.1
Free Float	87.4%
Average Daily Value (mn)	21.65 USD
BofA Ticker / Exchange	SAGE / NAS
Bloomberg / Reuters	SAGE US / SAGE.OQ
ROE (2024E)	-57.4%
Net Dbt to Eqty (Dec-2023A)	-9.0%
ESGMeter <sup>TM</sup>	Medium

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology".

See inside for abbreviations

# iQprofile<sup>SM</sup> SAGE Therapeutics

## iQmethod<sup>SM</sup> – Bus Performance\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-32.0%	-47.4%	-51.6%	-46.4%	-50.9%
Return on Equity	-35.7%	-52.8%	-57.4%	-51.6%	-56.7%
Operating Margin	-7,116.7%	-670.7%	-1,941.8%	-264.6%	-155.9%
Free Cash Flow	(461)	(541)	(370)	(213)	(136)

## iQmethod<sup>SM</sup> – Quality of Earnings\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0.8x	0.4x	0.5x	0.6x	0.7x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-13.0%	-9.0%	-34.7%	-45.7%	-55.2%
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	8	86	22	107	139
% Change	21.8%	1,024.8%	-74.2%	381.4%	29.8%
Gross Profit	8	86	22	107	139
% Change	21.8%	NM	-74.2%	381.4%	29.8%
EBITDA	(546)	(578)	(431)	(282)	(214)
% Change	-19.5%	-6.0%	25.5%	34.6%	23.9%
Net Interest & Other Income	14	39	38	38	38
<b>Net Income (Adjusted)</b>	<b>(533)</b>	<b>(541)</b>	<b>(395)</b>	<b>(247)</b>	<b>(180)</b>
<b>% Change</b>	<b>-16.4%</b>	<b>-1.6%</b>	<b>27.0%</b>	<b>37.7%</b>	<b>27.1%</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(533)	(541)	(395)	(246)	(179)
Depreciation & Amortization	1	1	2	2	3
Change in Working Capital	6	(67)	(44)	(42)	(41)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	66	66	67	75	83
Capital Expenditure	(1)	(1)	(1)	(1)	(2)
<b>Free Cash Flow</b>	<b>-461</b>	<b>-541</b>	<b>-370</b>	<b>-213</b>	<b>-136</b>
<b>% Change</b>	<b>-21.8%</b>	<b>-17.4%</b>	<b>31.6%</b>	<b>42.6%</b>	<b>36.0%</b>
Share / Issue Repurchase	3	6	159	14	20
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

## Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	163	72	201	172	142
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	1,174	797	456	285	200
Property, Plant & Equipment	3	2	9	17	25
Other Non-Current Assets	17	11	0	0	0
<b>Total Assets</b>	<b>1,356</b>	<b>882</b>	<b>666</b>	<b>474</b>	<b>367</b>
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	99	83	87	98	110
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	5	0	0	0	0
<b>Total Liabilities</b>	<b>104</b>	<b>83</b>	<b>87</b>	<b>98</b>	<b>110</b>
<b>Total Equity</b>	<b>1,253</b>	<b>800</b>	<b>579</b>	<b>377</b>	<b>257</b>
<b>Total Equity &amp; Liabilities</b>	<b>1,356</b>	<b>882</b>	<b>666</b>	<b>474</b>	<b>367</b>

\* For full definitions of iQmethod<sup>SM</sup> measures, see page 5.

## Company Sector

Biotechnology

## Company Description

Sage Therapeutics (SAGE) is a clinical-stage biopharmaceutical company focused on diseases affecting the central nervous system (CNS). Based in Boston, SAGE has a drug portfolio that modulates the gamma-aminobutyric acid (GABA) system. Zulresso is already approved for postpartum depression. Orally dosed Zuranolone is approved in postpartum depression and the company is exploring next steps in major depressive disorder.

## Investment Rationale

We rate SAGE shares Neutral. We believe in zuranolone's differentiated profile for depressive disorders but look for clarity on commercial opportunity after the approval of zuranolone in post-partum depression but denial in major depressive, which is a much larger indication. We await next steps regarding additional clinical trials in MDD and timing, as well as better understanding of pricing and market penetration in PPD.

## Stock Data

Average Daily Volume 940,619

## Quarterly Earnings Estimates

	2023	2024
Q1	-2.46A	-1.60E
Q2	-2.68A	-1.62E
Q3	-3.37A	-1.62E
Q4	-0.55A	-1.61E

## Abbreviations

mgmt: management

OBGYN: Obstetrician gynecologist

oppy: opportunity

PCP: primary care providers

PPD: Post-partum depression

pts: patients

## Price objective basis & risk

### SAGE Therapeutics (SAGE)

Our discounted cash flow (DCF)-derived PO of \$29 for SAGE consists of \$0.1/share for Zulresso in PPD. Zuranolone contributes \$12/share to our PO for PPD and \$4/share in MDD. The remaining value in our PO comes from cash (\$12/sh), corporate expenses and pipeline (-\$1/sh) milestones (\$2/sh). We use a 9% weighted-average cost of capital (WACC) for Zulresso, a 9% WACC for Zuranolone in PPD, and 11% WACC in MDD, and assume no terminal value for SAGE.

Upside risks to our price objective are 1) approval of zuranolone in MDD, 2) higher-than-expected penetration of zuranolone in PPD and MDD, and 3) positive data from early stage assets.

Downside risks are 1) failure of Zuranolone in MDD, 2) failure of other clinical programs, and 3) lower-than-expected penetration of zuranolone and Zulresso

## Analyst Certification

I, Tazeen Ahmad, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

### US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>BUY</b>				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	Ocular Therapeutix	OCUL	OCUL US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
<b>NEUTRAL</b>				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
<b>UNDERPERFORM</b>				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad

## iQmethod<sup>SM</sup> Measures Definitions

### Business Performance

Return On Capital Employed

Return On Equity

Operating Margin

Earnings Growth

Free Cash Flow

### Quality of Earnings

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

### Valuation Toolkit

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

EV / EBITDA

### Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income

Operating Profit

Expected 5 Year CAGR From Latest Actual

Cash Flow From Operations – Total Capex

### Numerator

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash &amp; Equivalents

EBIT

### Numerator

Current Share Price

Current Share Price

Annualised Declared Cash Dividend

Cash Flow From Operations – Total Capex

EV = Current Share Price × Current Shares + Minority Equity + Net Debt +

Other LT Liabilities

Enterprise Value

### Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill

Amortization

Shareholders' Equity

Sales

N/A

N/A

### Denominator

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

### Denominator

Diluted Earnings Per Share (Basis As Specified)

Shareholders' Equity / Current Basic Shares

Current Share Price

Market Cap = Current Share Price × Current Basic Shares

Sales

Basic EBIT + Depreciation + Amortization

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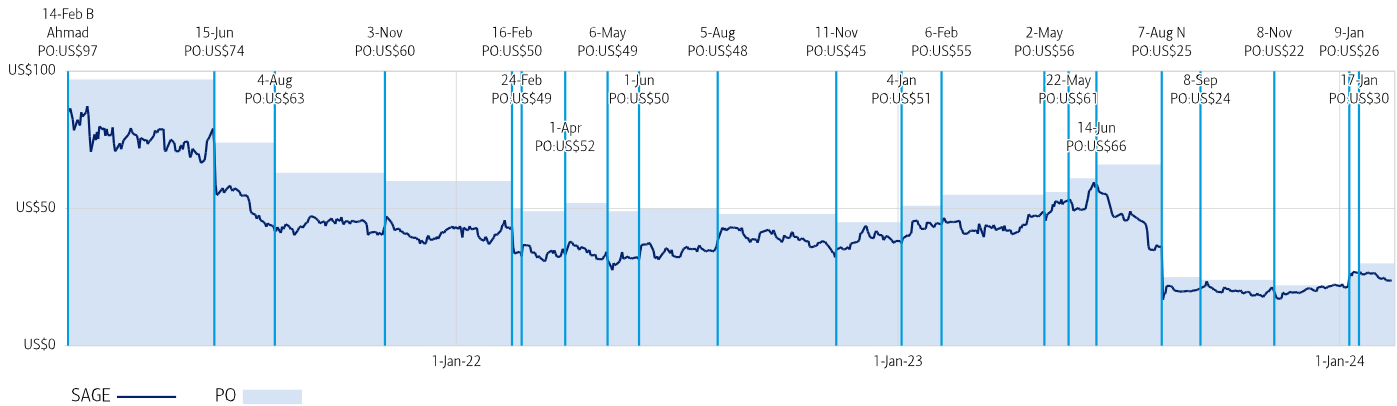
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### SAGE Therapeutics (SAGE) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

### Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

### Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

<sup>R1</sup> Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Neutral	≥ 0%	≤ 30%
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