

Axsome Therapeutics

Increase PO to reflect 4Q Auvelity MDD + pipeline tweaks; Reiterate Neutral

Reiterate Rating: NEUTRAL | PO: 95.00 USD | Price: 89.20 USD

PO to \$95 to reflect MDD launch + pipeline advancement

We update our Axsome (AXSM) model to reflect the ongoing Auvelity-MDD launch which is tracking slightly ahead of our expectations and we model higher risk-adj. value for several pipeline programs. The drivers of our PO increase are: 1) Auvelity MDD sales now peak at \$1.3bn from prior \$1.2bn, after a 4Q beat; 2) we add Sunosi-ADHD to our sales forecast ahead of Ph3. While we see the commercial opportunity as more niche, we see ADHD as a leverage-play given AXSM's psych presence; 3) Ph3 ADA – POS increase as we believe currently completed studies satisfy AXSM's efficacy requirement for indication. We remain Neutral as we see balanced risk/reward with upside around pipeline offset by Auvelity-MDD tracking below cons peak.

Balanced setup: MDD cons risk vs. '24 pipeline events

Auvelity for MDD (depression) is set to generate ~\$130m in 2023 revenues after a 4Q22 launch. Overall, we think Axsome has done a good job of out-pacing Yr-1 sell-side cons expectations on better net pricing /payer reimbursement. However, in the out-years, we believe Auvelity S&M investments (more reps) will need to drive an acceleration in scripts if cons projections are going to be achieved (Exhibit 1). While we see some risk around Auvelity-MDD hitting consensus out-year numbers, we believe this is counterbalanced by pipeline catalysts including 1) 1H24 Ph3 Auvelity-ADA data we view as low risk – the study is a replica of ADVANCE-1 and likely isn't needed to satisfy the efficacy requirement for approval; 2) Ph3 AXS-12 for narcolepsy and Ph3 Sunosi for ADHD are both high probability studies, though we see both as commercially niche.

Model updates: Auvelity peak sales + risk-adj. pipeline add

As noted, our AXSM model updates are broad based and include the following: 1) Auvelity-MDD: we reflect a better ramp and slightly better peak at \$1.3bn (vs prior \$1.2bn) [+\$/sh] but we're below consensus 2030 by 14%; 2) add Sunosi ADHD which we forecast \$350m nominal peak sales which should partially leverage existing psychiatry sales force [+\$/sh]; 3) tweak pipeline probabilities of success – Auvelity-ADA to 90% (prior 80%) [+\$/sh] and higher POS for fibromyalgia (AXS-14) and narcolepsy (AXS-12) to reflect development status [total +\$/sh].

See pg. 3 for exhibits.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(3.47)	(4.60)	(4.13)	(3.25)	1.68
EPS Change (YoY)	-25.3%	-32.6%	10.2%	21.3%	NM
Consensus EPS (Bloomberg)			(4.27)	(3.13)	1.95
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	53.1x
EV / EBITDA*	NM	NM	NM	NM	32.7x
Free Cash Flow Yield*	-2.6%	-2.8%	-4.4%	-2.4%	3.5%

* For full definitions of IQMethodSM measures, see page 5.

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Timestamp: 11 January 2024 04:31PM EST

11 January 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	80.00	95.00
2023E Rev (m)	269.6	270.4
2024E Rev (m)	370.3	405.8
2025E Rev (m)	704.9	821.0
2023E EPS	-4.14	-4.13
2024E EPS	-3.00	-3.25
2025E EPS	1.42	1.68

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Stock Data

Price	89.20 USD
Price Objective	95.00 USD
Date Established	11-Jan-2024
Investment Opinion	C-2-9
52-Week Range	53.71 USD - 92.19 USD
Mrkt Val (mn) / Shares Out (mn)	4,221 USD / 47.3
Free Float	81.5%
Average Daily Value (mn)	62.97 USD
BofA Ticker / Exchange	AXSM / NAS
Bloomberg / Reuters	AXSM US / AXSM.OQ
ROE (2023E)	-77.5%
Net Dbt to Eqty (Dec-2022A)	-91.5%
ESGMeter TM	Low

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".

Acronyms:

ADA: alzheimer's disease agitation
ADHD: attention-deficit/hyperactivity

iQprofileSM Axsome Therapeutics

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-53.6%	-101.2%	-42.8%	-33.1%	27.1%
Return on Equity	-206.4%	-298.9%	-77.5%	-51.9%	29.3%
Operating Margin	NA	-344.2%	-62.4%	-35.0%	14.0%
Free Cash Flow	(109)	(119)	(187)	(103)	148

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	2.0x
Asset Replacement Ratio	0.3x	0.3x	1.4x	1.5x	2.3x
Tax Rate	NM	NM	NM	NM	21.0%
Net Debt-to-Equity Ratio	-235.1%	-91.5%	-83.3%	-83.3%	-102.3%
Interest Cover	-43.9x	-23.5x	-25.0x	-47.3x	NM

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	0	50	270	406	821
% Change	NA	NA	440.1%	50.1%	102.3%
Gross Profit	0	45	251	369	747
% Change	NA	NA	459.8%	47.1%	102.2%
EBITDA	(124)	(170)	(166)	(138)	120
% Change	-25.9%	-37.8%	2.2%	16.9%	NM
Net Interest & Other Income	(6)	(15)	(17)	(13)	(12)
Net Income (Adjusted)	(130)	(187)	(187)	(155)	81
% Change	-26.7%	-43.5%	-0.1%	17.1%	NM

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(130)	(187)	(187)	(155)	81
Depreciation & Amortization	1	2	2	4	5
Change in Working Capital	0	29	(29)	30	55
Deferred Taxation Charge	0	0	0	0	0
Other Adjustments, Net	21	38	30	24	19
Capital Expenditure	0	(1)	(3)	(5)	(11)
Free Cash Flow	-109	-119	-187	-103	148
% Change	-28.5%	-9.5%	-57.5%	45.0%	NM
Share / Issue Repurchase	12	175	225	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	45	(16)	(38)	(38)

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	86	201	396	255	365
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	0	45	45	45	45
Property, Plant & Equipment	0	1	4	8	16
Other Non-Current Assets	1	85	85	85	85
Total Assets	88	331	529	392	511
Short-Term Debt	1	6	6	7	8
Other Current Liabilities	22	90	61	90	144
Long-Term Debt	49	94	79	60	22
Other Non-Current Liabilities	0	31	10	10	10
Total Liabilities	72	222	156	167	184
Total Equity	16	110	374	225	327
Total Equity & Liabilities	88	331	529	392	511

* For full definitions of iQmethodSM measures, see page 5.

Company Sector

Biotechnology

Company Description

Axsome Therapeutics (AXSM) is a clinical-stage company focused on developing drugs for treatment of central nervous system (CNS) disorders. Axsome's pipeline consists of one commercialized drug and four drugs that are in mid/late-stage of clinical development.

Investment Rationale

We are Neutral-rated on AXSM stock based on our view that there is a balanced risk/reward where Axsome's Auvelity launch as a treatment for MDD risks tracking below consensus expectations and we see the company's primary care products are relatively undifferentiated (depression, narcolepsy, migraine). On the flip side, we see these negatives as being counter-balanced by likely positive Ph3 updates for AXS-12 (narcolepsy) and Auvelity third Alzheimer's agitation readout (1H24).

Stock Data

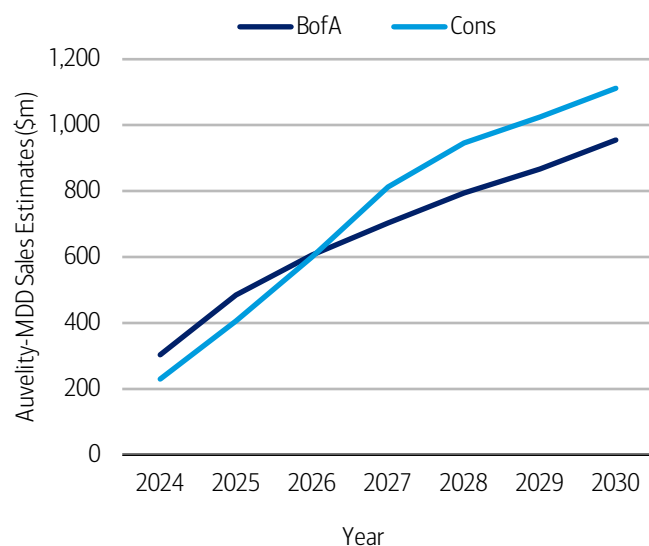
Average Daily Volume 705,924

Quarterly Earnings Estimates

	2022	2023
Q1	-1.03A	NAA
Q2	-1.06A	NAA
Q3	-1.07A	NAA
Q4	-1.41A	NAE

Exhibit 1: BofA vs Cons Sales estimates for Auvelity-MDD

We are tracking below cons in out years (2030e) MDD sales estimates.

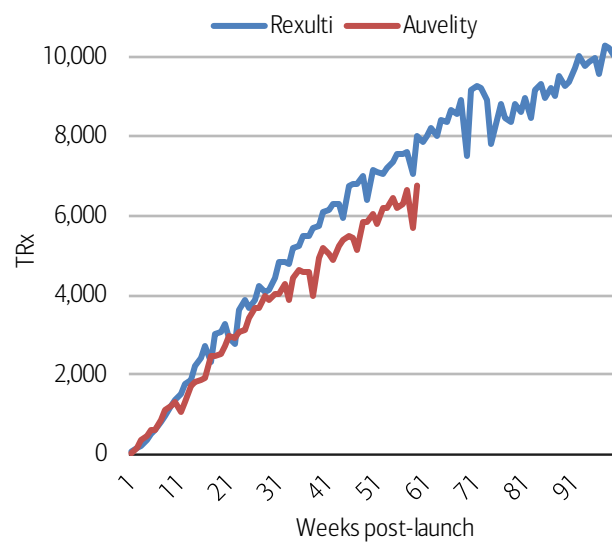


Source: VisibleAlpha; BofA Research

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Exhibit 2: Comparison of Auvelity to brand analog Rexulti, which achieved ~\$900m Yr-7 MDD sales

Auvelity is tracking slightly (low teen %) below analog Rexulti when compared on a week-post launch basis.



Source: BBG Symphony; BofA Research

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Price objective basis & risk

Axsome Therapeutics (AXSM)

Our \$95 price objective (PO) is based on a risk-adjusted SOTP analysis. Key assumptions: 1) total (nominal) product sales reach \$1.7bn by 2027E, 2) no terminal value as we forecast sales through expected drug LOE, 3) 9.5% discount rate. For Sunosi - in EDS, we model \$335m in peak sales (commercial, fully derisked) and in ADHD, we model \$350m in nominal peak sales. Our AXS-05 (Auvelity) peak sales for depression are \$1.3bn. For AXS-05 in Alzheimer's agitation, we model \$1.5bn in risk-adjusted peak-sales. For migraine, we model \$170m in risk-adjusted peak sales for AXS-07. We model AXS-12 narcolepsy risk-adj. peak-sales estimate at \$270m. For AXS-14 in fibromyalgia, we model \$240m in risk-adj. peak-sales.

Upside risks to our PO: 1) better-than-expected commercial uptake, 2) pipeline validation beyond our assumptions, 3) potential competitive setbacks.

Downside risks to our PO: 1) lower-than-expected commercial uptake of Auvelity in MDD, 2) competitive assets generating significantly better data vs AXSM, 3) potential setbacks on Axsome's execution on pipeline clinical development plan.

Analyst Certification

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US - Specialty Pharma & Biotechnology Coverage Cluster

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	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculus Holding AG	OCS	OCS US	Jason M. Gerberry
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	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
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IQmethodSM 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 & 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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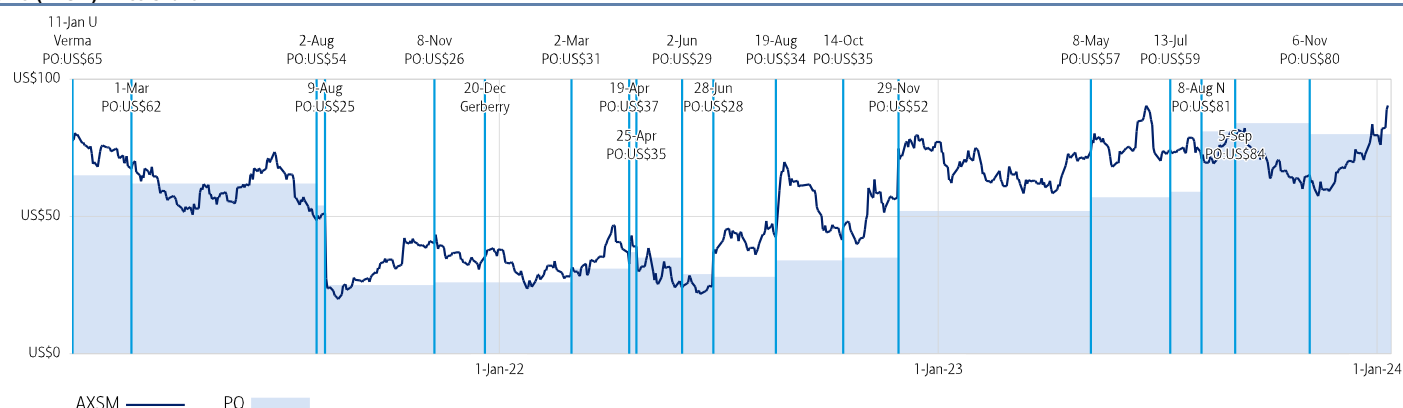
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Axsome (AXSM) Price Chart



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.

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Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	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%

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Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	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%

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