

## Axsome Therapeutics

## 4Q EPS: ADA minor timeline push, nothing thesis-changing

Reiterate Rating: NEUTRAL | PO: 96.00 USD | Price: 92.81 USD

## 4Q largely uneventful outside of ADA timeline push

Axsome (AXSM) shares are a notable underperformer (-10% vs XBI -0.2%) following a 4Q update highlighted by a Ph3 Auvelity ADA timeline push (readout now 2H24 from 1H24). Given 4Q results were pre-announced and AXSM does not offer 2024 guidance, we do not believe today's stock move was driven by financial results. Both we/Street forecast Auvelity sales to grow meaningfully ~+100% Y/Y ('24 Auvelity BofA \$260m vs cons \$266m), driven by large end-market and +100 person salesforce expansion. On the key pipeline update, the Advance-2 delay was attributed to slower enrollment in the community setting though mgmt remains confident it will report topline data in 2024. Based on 4Q updates, we smooth our FY24 OpEx to reflect pipeline program execution and expected SG&A spend and push our ADA launch to 2026. Our PO remains unchanged at \$96; we reiterate Neutral on balanced risk/reward.

## ADA readout pushed to 2H24, citing evolving SOC

Management attributed the Advance-2 readout delay to slower patient enrollment in the community setting (focus of enrollment). On the call, management discussed the commercial rollout of Otsuka's Rexulti for ADA as the key issue given Advance-2 is focused on enrolling Rexulti-naïve patients. While we have not seen any major inflection in Rexulti usage (post-launch) on a TRx-basis (Exhibit 1), AXSM cited Rexulti claims data (in Medicare channel) as proof of a launch inflection. In our view, careful patient selection for ADA trials is important given the patient heterogeneity can impact placebo response rates. Our high POS for Auvelity in ADA (90%) is supported by strength of clinical data from Advance-1 and Accord and our 2026e launch is on the premise of a sNDA submission gated by OLE safety data in '25.

## Auvelity-MDD launch: no forward guidance

On the Auvelity-MDD launch, management indicated it has no plans to offer forward looking guidance in 2024. On net pricing (GtN), while Auvelity fared slightly better in 4Q than prior Qs (+5% delta), mgmt expects GtN to worsen in 1Q given seasonality dynamics. Otherwise, Auvelity payer contracting remained stagnant in 4Q (70% of lives contracted; 48% commercial/100% government), similar to the prior two quarters. On the Auvelity salesforce expansion, cost of the field force was only partially reflected in 4Q OpEx and will be a source of upward SG&A increase in '24.

Note continued on page 3.

| Estimates (Dec) (US\$)    | 2021A  | 2022A  | 2023E  | 2024E  | 2025E  |
|---------------------------|--------|--------|--------|--------|--------|
| EPS                       | (3.47) | (4.60) | (5.28) | (4.56) | 0.54   |
| EPS Change (YoY)          | -25.3% | -32.6% | -14.8% | 13.6%  | NM     |
| Consensus EPS (Bloomberg) |        |        | (4.26) | (3.12) | 1.48   |
| DPS                       | 0      | 0      | 0      | 0      | 0      |
| <b>Valuation (Dec)</b>    |        |        |        |        |        |
| P/E                       | NM     | NM     | NM     | NM     | 171.9x |
| EV / EBITDA*              | NM     | NM     | NM     | NM     | 43.6x  |
| Free Cash Flow Yield*     | -2.5%  | -2.7%  | -5.3%  | -4.0%  | 1.6%   |

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

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20 February 2024

## Equity

## Key Changes

| (US\$)        | Previous | Current |
|---------------|----------|---------|
| 2023E Rev (m) | 270.4    | 270.1   |
| 2025E Rev (m) | 723.1    | 643.8   |
| 2023E EPS     | -4.13    | -5.28   |
| 2024E EPS     | -2.94    | -4.56   |
| 2025E EPS     | 1.43     | 0.54    |

Jason M. Gerberry

Research Analyst  
BofAS  
+1 646 743 0180  
[jason.gerberry@bofa.com](mailto:jason.gerberry@bofa.com)

Dina Ramadane

Research Analyst  
BofAS  
[dina.ramadane@bofa.com](mailto:dina.ramadane@bofa.com)

Chi M. Fong

Research Analyst  
BofAS  
[chi.fong@bofa.com](mailto:chi.fong@bofa.com)

Pavan R. Patel

Research Analyst  
BofAS  
[pavan.r.patel@bofa.com](mailto:pavan.r.patel@bofa.com)

## Stock Data

|                                |                       |
|--------------------------------|-----------------------|
| Price                          | 92.81 USD             |
| Price Objective                | 96.00 USD             |
| Date Established               | 24-Jan-2024           |
| Investment Opinion             | C-2-9                 |
| 52-Week Range                  | 53.71 USD - 98.40 USD |
| Mkt Val (mn) / Shares Out (mn) | 4,392 USD / 47.3      |
| Free Float                     | 81.5%                 |
| Average Daily Value (mn)       | 56.17 USD             |
| BofA Ticker / Exchange         | AXSM / NAS            |
| Bloomberg / Reuters            | AXSM US / AXSM.OQ     |
| ROE (2023E)                    | -111.3%               |
| Net Dbt to Eqty (Dec-2022A)    | -91.5%                |
| ESGMeter <sup>TM</sup>         | 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

GtN: gross-to-net pricing

MDD: major depressive disorder

OLE: open label extension

OpEx: operating expenses

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

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

| (US\$ Millions)            | 2021A   | 2022A   | 2023E   | 2024E   | 2025E |
|----------------------------|---------|---------|---------|---------|-------|
| Return on Capital Employed | -53.6%  | -101.2% | -48.5%  | -47.7%  | 36.9% |
| Return on Equity           | -206.4% | -298.9% | -111.3% | -101.2% | 19.4% |
| Operating Margin           | NA      | -344.2% | -65.5%  | -44.1%  | 14.0% |
| Free Cash Flow             | (109)   | (119)   | (233)   | (178)   | 71    |

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

| (US\$ Millions)          | 2021A   | 2022A  | 2023E  | 2024E  | 2025E  |
|--------------------------|---------|--------|--------|--------|--------|
| Cash Realization Ratio   | NM      | NM     | NM     | NM     | 3.1x   |
| Asset Replacement Ratio  | 0.3x    | 0.3x   | 1.4x   | 1.3x   | 1.9x   |
| Tax Rate                 | NM      | NM     | NM     | NM     | 21.0%  |
| Net Debt-to-Equity Ratio | -235.1% | -91.5% | -82.7% | -61.1% | -86.8% |
| Interest Cover           | -43.9x  | -23.5x | -27.4x | NM     | 45.0x  |

## Income Statement Data (Dec)

| (US\$ Millions)              | 2021A         | 2022A         | 2023E         | 2024E        | 2025E     |
|------------------------------|---------------|---------------|---------------|--------------|-----------|
| Sales                        | 0             | 50            | 270           | 362          | 644       |
| % Change                     | NA            | NA            | 439.6%        | 34.1%        | 77.7%     |
| Gross Profit                 | 0             | 45            | 244           | 329          | 586       |
| % Change                     | NA            | NA            | 444.0%        | 35.0%        | 77.8%     |
| EBITDA                       | (124)         | (170)         | (175)         | (156)        | 95        |
| % Change                     | -25.9%        | -37.8%        | -2.6%         | 10.6%        | NM        |
| Net Interest & Other Income  | (6)           | (15)          | (62)          | (58)         | (57)      |
| <b>Net Income (Adjusted)</b> | <b>(130)</b>  | <b>(187)</b>  | <b>(240)</b>  | <b>(218)</b> | <b>26</b> |
| <b>% Change</b>              | <b>-26.7%</b> | <b>-43.5%</b> | <b>-28.1%</b> | <b>9.1%</b>  | <b>NM</b> |

## Free Cash Flow Data (Dec)

| (US\$ Millions)                        | 2021A         | 2022A        | 2023E         | 2024E        | 2025E     |
|--|---------------|--------------|---------------|--------------|-----------|
| Net Income from Cont Operations (GAAP) | (130)         | (187)        | (240)         | (218)        | 26        |
| Depreciation & Amortization            | 1             | 2            | 2             | 4            | 5         |
| Change in Working Capital              | 0             | 29           | (22)          | 17           | 29        |
| Deferred Taxation Charge               | 0             | 0            | 0             | 0            | 0         |
| Other Adjustments, Net                 | 21            | 38           | 30            | 24           | 19        |
| Capital Expenditure                    | 0             | (1)          | (3)           | (5)          | (9)       |
| <b>Free Cash Flow</b>                  | <b>-109</b>   | <b>-119</b>  | <b>-233</b>   | <b>-178</b>  | <b>71</b> |
| <b>% Change</b>                        | <b>-28.5%</b> | <b>-9.5%</b> | <b>-95.8%</b> | <b>23.6%</b> | <b>NM</b> |
| 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        | 350        | 134        | 167        |
| Trade Receivables                     | NA        | NA         | NA         | NA         | NA         |
| Other Current Assets                  | 0         | 45         | 45         | 45         | 45         |
| Property, Plant & Equipment           | 0         | 1          | 4          | 7          | 14         |
| Other Non-Current Assets              | 1         | 85         | 85         | 85         | 85         |
| <b>Total Assets</b>                   | <b>88</b> | <b>331</b> | <b>484</b> | <b>271</b> | <b>310</b> |
| Short-Term Debt                       | 1         | 6          | 6          | 7          | 8          |
| Other Current Liabilities             | 22        | 90         | 68         | 84         | 113        |
| Long-Term Debt                        | 49        | 94         | 79         | 60         | 22         |
| Other Non-Current Liabilities         | 0         | 31         | 10         | 10         | 10         |
| <b>Total Liabilities</b>              | <b>72</b> | <b>222</b> | <b>163</b> | <b>162</b> | <b>153</b> |
| <b>Total Equity</b>                   | <b>16</b> | <b>110</b> | <b>321</b> | <b>110</b> | <b>157</b> |
| <b>Total Equity &amp; Liabilities</b> | <b>88</b> | <b>331</b> | <b>484</b> | <b>271</b> | <b>310</b> |

\* For full definitions of iQmethod<sup>SM</sup> 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 605,194

## Quarterly Earnings Estimates

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

## Pipeline: other milestones reiterated

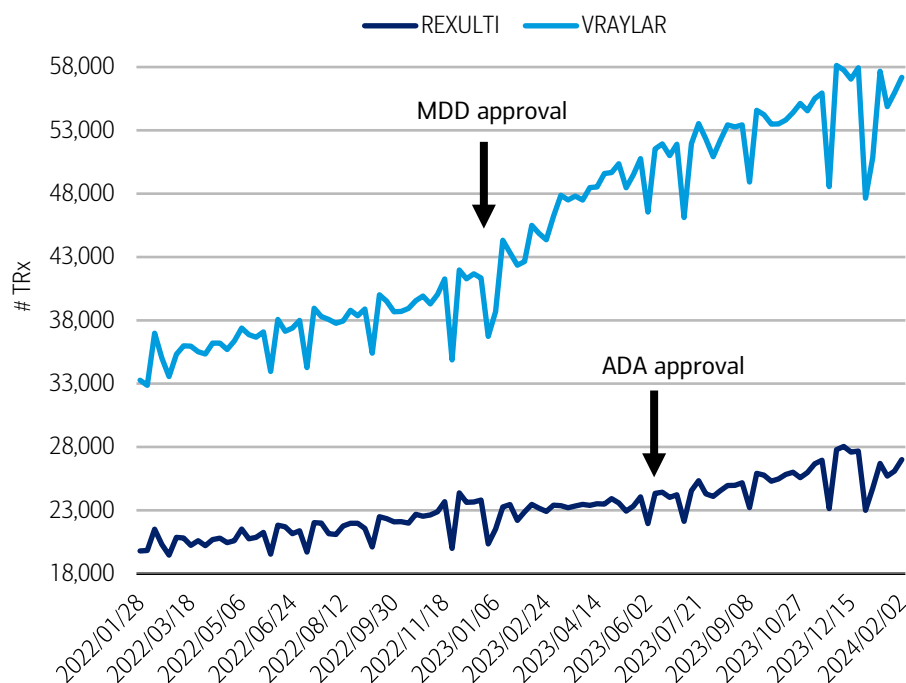
Outside of Advance-2 updates, pipeline programs remain on track with AXS-12 narcolepsy Ph3 readout expected in 1Q (imminently), which would lead to an NDA (New Drug Application) submission, if positive. AXSM mgmt refrained from providing expectations on AXS-12 pricing, though we view AXS-12's opportunity in narcolepsy as niche and estimate ~\$350m in peak sales (vs cons \$500m). Other '24 milestones include Ph3 solriamfetol Attention-Deficit-Hyperactivity Disorder (ADHD) topline in 2H24, AXS-14 fibromyalgia NDA submission in 2Q24, and AXS-07 migraine NDA resubmission in 1H24.

## Model changes: ADA push, OpEx

We update our AXSM model for 4Q23 financials and program updates. Our updates include: 1) smoothing Auvelity-MDD in 2024 to reflect a linear ramp for market adoption, 2) delay revenue recognition for Auvelity-ADA to 2026 (prior 2H25) to reflect topline data now in 2H24, 3) slightly increase SG&A and R&D (research and development) in 2024+ to reflect pipeline programs coming online and sales rep expansion. Model changes are summarized in Exhibit 2.

### Exhibit 1: Weekly script trends for Rexulti and Vraylar during label expansion period (MDD, ADA, respectively)

While Vraylar experienced a clear inflection point in script trend upon MDD approval, Rexulti scripts are growing at a slower ramp post-ADA approval (arrows)



Source: IQVIA, BofA Research

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### Exhibit 2: Summary of model changes

We summarize estimate changes made with this report

| Ticker | PO (\$) |     | Revenue (\$m) |       |       |         |       |       | EPS (\$) |       |       |         |       |       |
|--------|---------|-----|---------------|-------|-------|---------|-------|-------|----------|-------|-------|---------|-------|-------|
|        |         |     | Old           |       |       | Current |       |       | Old      |       |       | Current |       |       |
|        | Old     | New | 2024E         | 2025E | 2026E | 2024E   | 2025E | 2026E | 2024E    | 2025E | 2026E | 2024E   | 2025E | 2026E |
| AXSM   | 96      | 96  | 362           | 723   | 1,174 | 362     | 644   | 1,161 | (2.94)   | 1.43  | 5.06  | (4.56)  | 0.54  | 4.30  |

Source: BofA Global Research estimates

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## Price objective basis & risk

### Axsome Therapeutics (AXSM)

Our \$96 price objective (PO) is based on a risk-adjusted sum-of-the-parts (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-adjusted peak-sales estimate at \$400m. For AXS-14 in fibromyalgia, we model \$240m in risk-adjusted 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

I, Jason M. Gerberry, 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 - Specialty Pharma & Biotechnology Coverage Cluster

| Investment rating   | Company                   | BofA Ticker | Bloomberg symbol | Analyst           |
|---------------------|---------------------------|-------------|------------------|-------------------|
| <b>BUY</b>          |                           |             |                  |                   |
|                     | Arcellx, Inc.             | ACLX        | ACLX US          | Jason M. Gerberry |
|                     | Arrowhead Pharmaceuticals | ARWR        | ARWR US          | Jason M. Gerberry |
|                     | bluebird bio              | BLUE        | BLUE US          | Jason M. Gerberry |
|                     | Exelixis                  | EXEL        | EXEL US          | Jason M. Gerberry |
|                     | 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 |
|                     | Relay Therapeutics        | RLAY        | RLAY US          | Jason M. Gerberry |
|                     | Tarsus Pharmaceuticals    | TARS        | TARS US          | Jason M. Gerberry |
|                     | Teva Pharmaceuticals      | TEVA        | TEVA US          | Jason M. Gerberry |
|                     | Vaxcyte Inc               | PCVX        | PCVX US          | Jason M. Gerberry |
|                     | Xenon Pharmaceuticals     | XENE        | XENE US          | Jason M. Gerberry |
| <b>NEUTRAL</b>      |                           |             |                  |                   |
|                     | Alkermes                  | ALKS        | ALKS US          | Jason M. Gerberry |
|                     | Amphastar Pharmaceuticals | AMPH        | AMPH US          | Jason M. Gerberry |
|                     | Axsome Therapeutics       | AXSM        | AXSM US          | Jason M. Gerberry |
|                     | Galapagos                 | GLPG        | GLPG US          | Jason M. Gerberry |
|                     | ProKidney Corp            | PROK        | PROK US          | Jason M. Gerberry |
|                     | Roivant                   | ROIV        | ROIV US          | Chi M. Fong       |
| <b>UNDERPERFORM</b> |                           |             |                  |                   |
|                     | Bausch Health Cos Inc     | BHC         | BHC US           | Jason M. Gerberry |

## US - Specialty Pharma &amp; Biotechnology Coverage Cluster

| Investment rating | Company             | BofA Ticker | Bloomberg symbol | Analyst           |
|-------------------|---------------------|-------------|------------------|-------------------|
|                   | FibroGen Inc.       | FGEN        | FGEN US          | Jason M. Gerberry |
|                   | Harmony Biosciences | HRMY        | HRMY US          | Jason M. Gerberry |
|                   | Organon             | OGN         | OGN US           | Jason M. Gerberry |
|                   | Viartis Inc.        | VTRS        | VTRS US          | Jason M. Gerberry |

**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 & 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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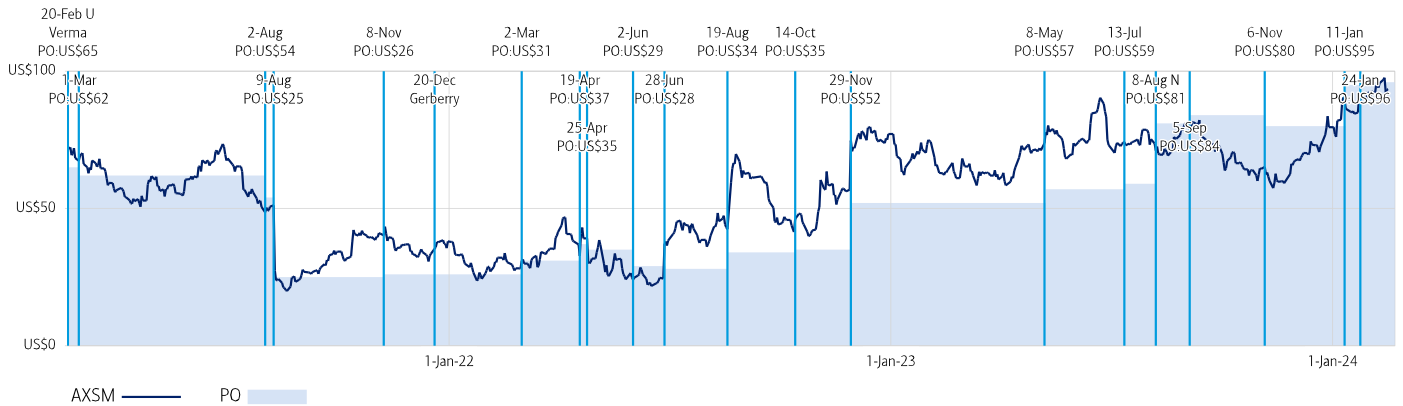
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# Disclosures

## Important Disclosures

### 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.

### 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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| Investment rating | Total return expectation (within 12-month period of date of initial rating) | Ratings dispersion guidelines for coverage cluster <sup>R2</sup> |
|-------------------|---|--|
| Buy               | ≥ 10%   | ≤ 70%  |
| Neutral           | ≥ 0%  | ≤ 30%  |
| Underperform      | N/A   | ≥ 20%  |

<sup>R2</sup> Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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