



Axsome Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

February 18, 2025

Total 4Q and full year 2024 net product revenue of \$118.8 million and \$385.7 million, respectively, representing 66% and 88% year-over-year growth
Auvelity® 4Q and full year 2024 net product sales of \$92.6 million and \$291.4 million, respectively, representing 89% and 124% year-over-year growth
Sunosi® 4Q and full year 2024 net product revenue of \$26.2 million and \$94.3 million, respectively, representing 16% and 26% year-over-year growth
Symbravo® approved in the U.S. for the acute treatment of migraine with or without aura in adults

Successful completion of Phase 3 clinical program of AXS-05 in Alzheimer's disease agitation announced; NDA submission anticipated in 2H 2025

Positive topline results of ENCORE Phase 3 trial of AXS-12 in narcolepsy announced; NDA submission anticipated in 2H 2025

Topline results of EMERGE Phase 3 trial of Symbravo in migraine in patients with prior inadequate response to oral CGRP inhibitors on track for 1Q 2025

Topline results of FOCUS and PARADIGM Phase 3 trials of solriamfetol in ADHD and MDD, respectively, on track for 1Q 2025

Company to host conference call today at 8:00 AM Eastern

NEW YORK, Feb. 18, 2025 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced financial results for the fourth quarter and full year of 2024 and provided a general business update.

"2024 was another defining year for Axsome, driven by strong commercial growth and a rapidly advancing late-stage pipeline, which culminated in the successful completion of our Phase 3 clinical program for AXS-05 in Alzheimer's disease agitation, and most recently, the U.S. approval of Symbravo last month for the acute treatment of migraine with or without aura in adults," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "With potentially five marketed products across six CNS indications of great unmet need over the next 12-18 months, we are well positioned to continue delivering innovative new medicines to patients, and significant near- and long-term value to shareholders."

Fourth Quarter and Full Year 2024 Financial Highlights

- Total net product revenues were \$118.8 million and \$385.7 million for the fourth quarter and full year of 2024, representing 66% and 88% year-over-year growth, respectively. Total net product revenues for the comparable periods in 2023 were \$71.5 million and \$204.9 million, respectively.
- Auvelity net product sales were \$92.6 million and \$291.4 million for the fourth quarter and full year of 2024, representing 89% and 124% year-over-year growth, respectively. Auvelity net product sales for the comparable periods in 2023 were \$49.0 million and \$130.1 million, respectively.
- Sunosi net product revenues were \$26.2 million and \$94.3 million for the fourth quarter and full year of 2024, representing 16% and 26% year-over-year growth, respectively, which consisted of \$24.7 million and \$90.3 million in net products sales and \$1.4 million and \$4.0 million in royalty and milestone revenue associated with Sunosi sales in out-licensed territories, respectively. Sunosi net product revenues for the comparable periods in 2023 were \$22.5 million and \$74.8 million, which consisted of \$21.7 million and \$72.4 million in net product sales, respectively.
- Total costs of revenue were \$10.5 million and \$33.3 million for the fourth quarter and full year of 2024, respectively. Total cost of revenue for the fourth quarter of 2024 included a one-time \$2.5 million sales-based milestone expense related to world-wide Sunosi sales. Total costs of revenue for the comparable periods in 2023 were \$7.4 million and \$26.1 million, respectively.
- Research and development (R&D) expenses were \$55.0 million and \$187.1 million for the fourth quarter and full year of 2024, respectively, compared to \$30.8 million and \$97.9 million for the comparable periods in 2023. The increase in R&D

expenses for the year was primarily related to the Company's ongoing Phase 3 trials of solriamfetol in ADHD, MDD, BED, and SWD, the advancement of Phase 3 trials of AXS-05 and AXS-12, manufacturing costs for AXS-07 and AXS-14, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Selling, general, and administrative (SG&A) expenses were \$113.3 million and \$411.4 million for the fourth quarter and full year of 2024, respectively, compared to \$86.8 million and \$323.1 million for the comparable periods in 2023. The increase in SG&A expenses for the year was primarily related to commercialization activities for Auvelity and Sunosi, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.
- Net loss for the fourth quarter of 2024 was \$74.9 million, or \$(1.54) per share, compared to a net loss of \$98.7 million, or \$(2.08) per share for the comparable period in 2023. The net loss in the fourth quarter of 2024 includes \$35.9 million in non-cash charges, primarily consisting of \$22.0 million in stock-based compensation expense, \$11.0 million in acquisition-related contingent consideration expense, and \$1.6 million in intangible asset amortization. Net loss for the full year of 2024 was \$287.2 million, or \$(5.99) per share, compared to a net loss of \$239.2 million, or \$(5.27) per share for the full year of 2023. The net loss for the full year of 2024 includes \$124.9 million in non-cash charges, including \$85.2 million in stock-based compensation expense, \$28.1 million in acquisition-related contingent consideration expense, and \$6.4 million in intangible amortization, compared to \$62.6 million, \$48.9 million, and \$6.4 million for the full year of 2023, respectively.
- Cash and cash equivalents totaled \$315.4 million at December 31, 2024, compared to \$386.2 million at December 31, 2023.
- Shares of common stock outstanding were 48,667,587 at December 31, 2024.

Financial Guidance

- Axsome believes that its current cash is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan.

Commercial Highlights

Auvelity

- Approximately 158,000 prescriptions were written for Auvelity in the fourth quarter of 2024, representing an increase of 87% compared to the same period in 2023, and an increase of 10% compared to the third quarter of 2024.
- Payer coverage for Auvelity across all channels is at approximately 78% of all covered lives. The proportion of lives covered for Auvelity in the commercial and government (Medicare and Medicaid) channels are approximately 63% and 100%, respectively.
- The previously announced expansion of the Auvelity psychiatry sales force from 260 to 300 sales representatives is now complete. The sales force expansion is expected to support continued growth within the primary care market and further improvements in payer coverage.

Sunosi

- Approximately 49,000 prescriptions were written for Sunosi in the U.S. in the fourth quarter of 2024, representing an increase of 16% compared to the same period in 2023, and an increase of 4% compared to the third quarter of 2024.
- Payer coverage for Sunosi across all channels is at approximately 83% of all covered lives. The proportion of lives covered for Sunosi in the commercial and government channels are approximately 95% and 60%, respectively.

Symbravo

- On January 30, 2025, the U.S. Food and Drug Administration (FDA) approved Symbravo for the acute treatment of migraine with or without aura in adults. Symbravo represents a novel, multi-mechanistic approach to treating migraine that targets multiple pathways underlying a migraine attack, and is engineered with Axsome's patented MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) rapid absorption technology. Pre-launch activities, including sales force hiring and payer discussions, are underway. The Company anticipates Symbravo to be commercially available in the U.S. in approximately four months.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of multiple, innovative, late-stage, patent-protected product candidates addressing a broad range of serious psychiatric and neurological conditions. Recent and anticipated progress for key pipeline programs is summarized below.

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for the treatment of Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 has been granted FDA Breakthrough Therapy designation for AD agitation.

- **Alzheimer's Disease Agitation:** Axsome has completed the Phase 3 clinical program of AXS-05 in Alzheimer's disease agitation consisting of four controlled Phase 3 efficacy trials and a long-term safety trial. AXS-05 demonstrated statistically significant improvements in Alzheimer's disease agitation compared to placebo in three efficacy trials (ADVANCE-1, ACCORD-1, and ACCORD-2), with supportive efficacy and controlled safety results in a fourth trial (ADVANCE-2). Based on the results from these studies, Axsome plans to submit a New Drug Application (NDA) for AXS-05 for the treatment of Alzheimer's disease agitation to the FDA in the second half of 2025.
- **Smoking Cessation:** Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in 2025.

Solriamfetol

Solriamfetol is Axsome's dopamine and norepinephrine reuptake inhibitor (DNRI), TAAR1 agonist, and 5-HT_{1A} agonist being developed for the treatment of attention deficit hyperactivity disorder (ADHD), major depressive disorder (MDD), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome is conducting the FOCUS study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in ADHD in adults. The Company is on track to report topline results from the FOCUS Phase 3 trial in the first quarter of 2025.
- **Major Depressive Disorder:** Axsome is conducting the PARADIGM study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in MDD. The study will examine the effect of solriamfetol in MDD patients with and without excessive daytime sleepiness (EDS). The Company is on track to report topline results from the PARADIGM Phase 3 trial in the first quarter of 2025.
- **Binge Eating Disorder:** Axsome is conducting the ENGAGE study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in BED. Based on current enrollment trends, the Company now anticipates topline results from the ENGAGE Phase 3 trial in 2026.
- **Shift Work Disorder:** Axsome is conducting the SUSTAIN study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in SWD in adults. The Company anticipates topline results from the SUSTAIN Phase 3 trial in 2026.

Symbravo

Symbravo (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, selective COX-2 inhibitor and 5-HT_{1B/1D} agonist indicated for the acute treatment of migraine with or without aura in adults.

- **Migraine:** Axsome is conducting the EMERGE study, a Phase 3, single-group, multicenter trial evaluating the efficacy and safety of Symbravo for the acute treatment of migraine in adults with a prior inadequate response to an oral CGRP inhibitor. The Company anticipates topline results from the EMERGE Phase 3 trial in the first quarter of 2025.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, investigational, highly selective and potent norepinephrine reuptake inhibitor and cortical dopamine modulator being developed for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for narcolepsy.

- **Narcolepsy:** Axsome has completed three controlled Phase 2 and Phase 3 efficacy trials and a long-term safety trial of AXS-12 in patients with narcolepsy with cataplexy. AXS-12 demonstrated statistically significant efficacy compared to placebo in all three efficacy trials (CONCERT, SYMPHONY, and ENCORE). Based on the results from these studies, Axsome plans to submit an NDA for AXS-12 for the treatment of cataplexy in patients with narcolepsy to the FDA in the second half of 2025.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, investigational, highly selective and potent norepinephrine reuptake inhibitor being developed for the management of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine.

- **Fibromyalgia:** Axsome plans to submit an NDA to the FDA for AXS-14 for the management of fibromyalgia in the first quarter of 2025.

Corporate Update

- In February 2025, Axsome announced that it has entered into a settlement agreement resolving all outstanding patent litigation related to Auvelity (dextromethorphan HBr – bupropion HCl). The litigation resulted from submission by Teva of an ANDA to the FDA seeking approval to market a generic version of Auvelity in the United States prior to the expiration of applicable Axsome patents. Under the terms of the settlement agreement, Axsome will grant Teva a license to sell its generic version of Auvelity beginning on or after March 31, 2039, if pediatric exclusivity is granted, or on or after September 30, 2038, if no pediatric exclusivity is granted, subject to FDA approval and conditions and exceptions customary for agreements of this type.

Anticipated Milestones

- **Regulatory and Commercial:**
 - AXS-14 for fibromyalgia, NDA submission (1Q 2025)
 - AXS-05 for Alzheimer's disease agitation, NDA submission (2H 2025)
 - AXS-12 for narcolepsy, NDA submission (2H 2025)
- **Clinical Trial Topline Results:**
 - Phase 3 EMERGE trial of AXS-07 in migraine in patients with inadequate response to oral CGRP inhibitors (1Q 2025)
 - Phase 3 FOCUS trial of solriamfetol in ADHD in adults (1Q 2025)
 - Phase 3 PARADIGM trial of solriamfetol in major depressive disorder (1Q 2025)
 - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (2026)
 - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2026)
- **Clinical Trial Initiations and Progress:**
 - Pivotal Phase 2/3 trial of AXS-05 in smoking cessation, initiation (2025)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its fourth quarter and full year 2024 financial results and provide a business update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic) or +1 (201) 389-0851 (international). A live webcast of the conference call can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at [axsome.com](https://www.axsome.com). A replay of the conference call will be available for approximately 30 days following the live event.

About Axsome Therapeutics

Axsome Therapeutics is a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) conditions. We deliver scientific breakthroughs by identifying critical gaps in care and develop differentiated products with a focus on novel mechanisms of action that enable meaningful advancements in patient outcomes. Our industry-leading neuroscience portfolio includes FDA-approved treatments for major depressive disorder and excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea and multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States. Together, we are on a mission to solve some of the brain's biggest problems so patients and their loved ones can flourish.

Forward Looking Statements

Certain matters discussed in this press release are "forward-looking statements". The Company may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the commercial success of the Company's Sunosi®, Auvelity®, and Symbravo® products and the success of the Company's efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company's ability to maintain and expand payer coverage; the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company's ability to fully fund the Company's disclosed clinical trials, which assumes no material changes to the Company's currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials, and/or data readouts, and the number or type of studies or nature of results necessary to support the filing of a new drug application ("NDA") for any of the Company's current product candidates; the Company's ability to fund additional clinical trials to continue the advancement of the Company's product candidates; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, the Company's product candidates, including statements regarding the timing of any NDA submission; the Company's ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the Company's products and product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the commercialization of Sunosi, Auvelity, and Symbravo and for the Company's commercial launch of its other product candidates, if approved, and the potential impact on the Company's anticipated cash runway; the Company's ability to

convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, geo-political conflicts or a global pandemic and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

Axsome Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 315,353	\$ 386,193
Accounts receivable, net	142,001	94,820
Inventories, net	15,732	15,135
Prepaid and other current assets	11,978	8,115
Total current assets	485,064	504,263
Equipment, net	584	846
Right-of-use asset - operating lease	5,383	6,772
Goodwill	12,042	12,042
Intangible asset, net	46,894	53,286
Non-current inventory and other assets	18,531	11,027
Total assets	\$ 568,498	\$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 71,997	\$ 40,679
Accrued expenses and other current liabilities	147,987	90,501
Operating lease liability, current portion	1,835	1,267
Contingent consideration, current	8,285	6,407
Total current liabilities	230,104	138,854
Contingent consideration, non-current	91,680	73,300
Loan payable, long-term	180,710	178,070
Operating lease liability, long-term	6,046	7,035
Finance lease liability, long-term	2,943	—
Total liabilities	511,483	397,259
Stockholders' equity:		
Preferred stock, \$0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding)	—	—
Common stock, \$0.0001 par value per share (150,000,000 shares authorized, 48,667,587 and 47,351,363 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,179,797	1,026,543
Accumulated deficit	(1,122,787)	(835,571)
Total stockholders' equity	57,015	190,977
Total liabilities and stockholders' equity	\$ 568,498	\$ 588,236

Axsome Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	\$ 117,325	\$ 70,747	\$ 381,677	\$ 202,460
License revenue	—	—	—	65,735

Royalty and milestone revenue	1,441	784	4,016	2,405
Total revenues	<u>118,766</u>	<u>71,531</u>	<u>385,693</u>	<u>270,600</u>
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	10,514	7,377	33,303	26,065
Research and development	55,006	30,803	187,077	97,944
Selling, general and administrative	113,271	86,810	411,359	323,123
Loss in fair value of contingent consideration	10,985	43,207	28,124	48,918
Intangible asset amortization	<u>1,607</u>	<u>1,607</u>	<u>6,392</u>	<u>6,375</u>
Total operating expenses	<u>191,383</u>	<u>169,804</u>	<u>666,255</u>	<u>502,425</u>
Loss from operations	(72,617)	(98,273)	(280,562)	(231,825)
Interest expense, net	(2,210)	(703)	(6,569)	(6,453)
Loss before income taxes	(74,827)	(98,976)	(287,131)	(238,278)
Income tax benefit (expense)	<u>(85)</u>	<u>325</u>	<u>(85)</u>	<u>(960)</u>
Net loss	<u>\$ (74,912)</u>	<u>\$ (98,651)</u>	<u>\$ (287,216)</u>	<u>\$ (239,238)</u>
Net loss per common share, basic and diluted	<u>\$ (1.54)</u>	<u>\$ (2.08)</u>	<u>\$ (5.99)</u>	<u>\$ (5.27)</u>
Weighted average common shares outstanding, basic and diluted	<u>48,541,905</u>	<u>47,329,782</u>	<u>47,914,253</u>	<u>45,425,212</u>

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Source: Axsome Therapeutics, Inc.