Axsome Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

May 5, 2025

Total 1Q 2025 net product revenue of $121.5 million, representing 62% year-over-year growth

AUVELITY® 1Q 2025 net product sales of $96.2 million, representing 80% year-over-year growth

SUNOSI® 1Q 2025 net product revenue of $25.2 million, representing 17% year-over-year growth

SYMBRAVO® approved for the acute treatment of migraine; commercial launch on track for June 2025

NDA for AXS-14 for the management of fibromyalgia submitted to the FDA

Supplemental NDA submission for AXS-05 in Alzheimer's disease agitation on track for 3Q 2025

NDA submission for AXS-12 for cataplexy in patients with narcolepsy anticipated in 2H 2025

Positive topline results of FOCUS Phase 3 trial of solriamfetol in ADHD announced

Initiation of Phase 3 trial of solriamfetol in major depressive disorder with excessive daytime sleepiness anticipated in 2025

Positive topline results of EMERGE Phase 3 trial of SYMBRAVO in migraine patients with prior inadequate response to oral CGRP inhibitors announced

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

NEW YORK, May 05, 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 first quarter of 2025 and provided a general business update.

"The first quarter was strong and eventful, with the approval of SYMBRAVO for the acute treatment of migraine, continued growth of AUVELITY and SUNOSI, and significant advancements across our broad late-stage neuroscience pipeline," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "Commercial availability of SYMBRAVO is on track for this June, and preparations are underway to enable a successful launch. We have submitted our NDA for AXS-14 for the management of fibromyalgia, and are on track for our planned NDA submissions this year for AXS-05 in Alzheimer's disease agitation and for AXS-12 in cataplexy in patients with narcolepsy. Our development programs with solriamfetol continue to advance, with the recently announced Phase 3 topline results in ADHD and MDD, and progress across the Phase 3 trials in binge eating disorder and excessive sleepiness associated with shift work disorder. Overall, our neuroscience portfolio positions us to deliver potentially five marketed products across ten indications that collectively impact over 150 million patients in the U.S. alone. We look forward to continued momentum over the balance of 2025 as we execute on our mission to deliver transformative medicines to patients living with serious CNS conditions."

First Quarter 2025 Financial Highlights

- Total net product revenue was $121.5 million for the first quarter of 2025, representing 62% year-over-year growth. Total net product revenue for the comparable period in 2024 was $75.0 million.
- AUVELITY net product sales were $96.2 million for the first quarter of 2025, representing 80% year-over-year growth. AUVELITY net product sales for the comparable period in 2024 were $53.4 million.
- SUNOSI net product revenue was $25.2 million for the first quarter of 2025, representing 17% year-over-year growth, which consisted of $24.1 million in net product sales and $1.1 million in royalty revenue associated with SUNOSI sales in out-licensed territories. SUNOSI net product revenue for the comparable period in 2024 was $21.6 million, which consisted of $20.7 million in net product sales and $0.9 million in royalty revenue.
- Total cost of revenue was $9.8 million for the first quarter of 2025. Total cost of revenue for the comparable period in 2024 was $6.3 million.
- Research and development (R&D) expenses were $44.8 million for the first quarter of 2025, compared to $36.8 million for the comparable period in 2024. The increase was primarily related to the Company's Phase 3 trials of solriamfetol,

manufacturing costs for the planned launch of SYMBRAVO, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Selling, general, and administrative (SG&A) expenses were $120.8 million for the first quarter of 2025, compared to $99.0 million for the comparable period in 2024. The increase was primarily related to commercialization activities for AUVELITY, including sales force and marketing expenses, pre-launch activities for SYMBRAVO, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Net loss for the first quarter of 2025 was $59.4 million, or $(1.22) per share, compared to a net loss of $68.4 million, or $(1.44) per share, for the comparable period in 2024. The net loss in the first quarter of 2025 includes $26.2 million in non-cash charges, comprised primarily of $23.3 million in stock-based compensation expense.

- Cash and cash equivalents totaled $300.9 million at March 31, 2025, compared to $315.4 million at December 31, 2024.

- Shares of common stock outstanding were 49,216,759 at March 31, 2025.

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 167,000 prescriptions were written for AUVELITY in the first quarter of 2025, representing an increase of 76% compared to the same period in 2024, and an increase of 5% compared to the fourth quarter of 2024.

- Payer coverage for AUVELITY across all channels is 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.

SUNOSI

- Approximately 46,000 prescriptions were written for SUNOSI in the U.S. in the first quarter of 2025, representing an increase of 12% compared to the same period in 2024, and a decrease of 5% compared to the fourth quarter of 2024.

- Payer coverage for SUNOSI across all channels is 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

- In January 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. Preparations for the commercial launch of SYMBRAVO remain on track, with commercial availability anticipated in June 2025.

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:** In March 2025, Axsome received formal pre-NDA meeting minutes from the FDA for AXS-05 in AD agitation, supporting a supplemental NDA (sNDA) submission. AXS-05 was granted Breakthrough Therapy designation for the treatment of AD agitation in June 2020. The Company is on track to submit the sNDA in the third quarter 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) with EDS, binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** In March 2025, Axsome announced positive topline results from the FOCUS Phase 3 trial evaluating the efficacy and safety of solriamfetol in ADHD in adults. The study achieved its primary and key secondary endpoints demonstrating substantial and statistically significant improvements in ADHD symptoms and disease severity with solriamfetol compared to placebo. Solriamfetol was safe and well tolerated in the trial, with a side effect profile consistent with the established safety profile of solriamfetol.

  The Company plans to initiate a Phase 3 trial of solriamfetol in ADHD in pediatric patients in 2025.

- **Major Depressive Disorder:** In April 2025, Axsome announced topline results from the PARADIGM Phase 3 proof-of-concept trial evaluating the efficacy and safety of solriamfetol in MDD with and without excessive daytime sleepiness (EDS). In the prespecified subgroup of patients with severe EDS, solriamfetol led to numerically greater improvements in depressive symptoms. Solriamfetol was safe and well tolerated in the trial, with a side effect profile consistent with the established safety profile of solriamfetol.

  The Company plans to initiate a Phase 3 trial of solriamfetol in MDD patients with EDS in 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. The Company 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:** In February 2025, Axsome announced positive topline results from the EMERGE Phase 3 open-label trial of SYMBRAVO in patients experiencing inadequate response to oral CGRP inhibitors. The study achieved its primary endpoint by demonstrating statistically significantly greater migraine treatment response with SYMBRAVO compared to prior oral CGRP inhibitors, as assessed by the Migraine Treatment Optimization Questionnaire (mTOQ-4). In the trial, SYMBRAVO rapidly and substantially improved migraine pain and most bothersome symptoms.

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 previously announced the completion of its clinical program of AXS-12 in patients with narcolepsy with cataplexy consisting of three controlled Phase 2 and Phase 3 efficacy trials and a long-term safety trial. AXS-12 achieved the primary endpoints and rapidly and substantially reduced cataplexy attacks, improved excessive daytime sleepiness, and improved cognitive function compared to placebo in all three efficacy trials (CONCERT, SYMPHONY, and ENCORE). The Company anticipates submitting an NDA 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 has submitted an NDA to the FDA for AXS-14 for the management of fibromyalgia. The Company anticipates the FDA's decision on acceptance of the filing in the second quarter of 2025.

Scientific Presentations

- In April 2025, Axsome presented the positive topline results from the ACCORD-2 Phase 3 trial of AXS-05 in Alzheimer's disease agitation and the SYMPHONY Phase 3 trial of AXS-12 in narcolepsy at the 2025 American Academy of Neurology (AAN) Annual Meeting. Additional presentations included findings from a new network meta-analysis comparing the efficacy of SYMBRAVO to oral CGRPs in the acute treatment of migraine.

Corporate Update

- In March 2025, Axsome announced that it resolved patent litigation with Hikma Pharmaceuticals USA, Inc. (Hikma) related to Hikma's Abbreviated New Drug Application (ANDA) for a generic version of SUNOSI. The Company entered into a license and settlement agreement with Hikma, which permits Hikma to begin selling its generic version of SUNOSI on or after September 1, 2040, if pediatric exclusivity is granted, or on or after March 1, 2040, 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:**
  - SYMBRAVO for the acute treatment of migraine, commercial launch (June 2025)
  - AXS-14 for fibromyalgia, FDA filing acceptance decision (2Q 2025)
  - AXS-05 for Alzheimer's disease agitation, sNDA submission (3Q 2025)
  - AXS-12 for narcolepsy, NDA submission (2H 2025)
- **Clinical Trial Topline Results:**
  - 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)
  - Phase 3 trial of solriamfetol in ADHD in pediatric patients, initiation (2025)
  - Phase 3 trial of solriamfetol in MDD with EDS, initiation (2025)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its first quarter 2025 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. 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, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, 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. For more information, please visit us at www.axsome.com and follow us on LinkedIn and X.

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 circumstances.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

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

	March 31, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 300,910	$ 315,353
Accounts receivable, net	161,398	142,001
Inventories, net	16,319	15,732
Prepaid and other current assets	16,007	11,978
Total current assets	494,634	485,064
Equipment, net	773	584
Right-of-use asset - operating lease	23,294	5,383
Goodwill	12,042	12,042
Intangible asset, net	45,322	46,894
Non-current inventory and other assets	20,606	18,531
Total assets	$ 596,671	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 85,659	$ 71,997
Accrued expenses and other current liabilities	149,199	147,987
Operating lease liability, current portion	454	1,835
Contingent consideration, current	8,602	8,285
Total current liabilities	243,914	230,104
Contingent consideration, non-current	90,590	91,680
Loan payable, long-term	181,377	180,710
Operating lease liability, long-term	23,905	6,046
Finance lease liability, long-term	3,680	2,943
Total liabilities	543,466	511,483
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, 49,216,759 and 48,667,587 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,235,400	1,179,797
Accumulated deficit	(1,182,200)	(1,122,787)
Total stockholders' equity	53,205	57,015
Total liabilities and stockholders' equity	$ 596,671	$ 568,498

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

	Three months ended March 31,	
	2025	2024

Revenues:		
Product sales, net	$ 120,358	$ 74,096
Royalty revenue	1,105	903
Total revenues	121,463	74,999
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	9,789	6,297
Research and development	44,785	36,830
Selling, general and administrative	120,787	98,970
Loss (Gain) in fair value of contingent consideration	1,512	(1,412)
Intangible asset amortization	1,572	1,589
Total operating expenses	178,445	142,274
Loss from operations	(56,982)	(67,275)
Interest expense, net	(2,431)	(1,082)
Loss before income taxes	(59,413)	(68,357)
Income tax expense	—	—
Net loss	$ (59,413)	$ (68,357)
Net loss per common share, basic and diluted	$ (1.22)	$ (1.44)
Weighted average common shares outstanding, basic and diluted	48,871,163	47,393,563

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Source: Axsome Therapeutics, Inc.