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

August 4, 2025

Total 2Q 2025 net product revenue of $150.0 million, representing growth of 72% year-over-year and 24% sequentially

AUVELITY® 2Q 2025 net product sales of $119.6 million, representing growth of 84% year-over-year and 24% sequentially

SUNOSI® 2Q 2025 net product revenue of $30.0 million, representing growth of 35% year-over-year and 19% sequentially

SYMBRAVO® launched June 10th, with 2Q 2025 net product sales of $0.4 million

AUVELITY® market access expanded by 28 million new covered lives in the commercial channel

First group purchasing organization (GPO) contract for SYMBRAVO® signed

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 4Q 2025

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

NEW YORK, Aug. 04, 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 second quarter of 2025 and provided a general business update.

"Axsome delivered robust second quarter performance, reflecting strong underlying demand for our life-changing medicines, exacting commercial execution, solid regulatory progress, and continued advancement of our differentiated neuroscience pipeline. We are excited by the recent approval and launch of SYMBRAVO for migraine, and are pleased with the accelerating performance of AUVELITY for depression and SUNOSI for excessive daytime sleepiness," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "We remain on track to submit new drug applications to the FDA for AXS-05 for Alzheimer's disease agitation in the third quarter, and for AXS-12 in narcolepsy in the fourth quarter. The rest of our development pipeline is advancing apace, including late-stage programs in ADHD, binge eating disorder, shift work disorder, depression associated with excessive daytime sleepiness, fibromyalgia, and smoking cessation. In total, our portfolio of potentially first-in-class or best-in-class medicines have the potential to address serious conditions that affect more than 150 million patients in the U.S. alone."

Financial Highlights

- Total net product revenue was $150.0 million for the second quarter of 2025, representing 72% year-over-year growth, and 24% sequential growth compared to the first quarter of 2025. Total net product revenue for the second quarter of 2024 was $87.2 million.

- AUVELITY net product sales were $119.6 million for the second quarter of 2025, representing 84% year-over-year growth, and 24% sequential growth compared to the first quarter of 2025. AUVELITY net product sales for the second quarter of 2024 were $65.0 million.

- SUNOSI net product revenue was $30.0 million for the second quarter of 2025, representing 35% year-over-year growth, and 19% sequential growth compared to the first quarter of 2025. SUNOSI net product revenue for the second quarter of 2025 consisted of $28.9 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 second quarter of 2024 was $22.1 million, which consisted of $21.5 million in net product sales and $0.6 million in royalty revenue.

- SYMBRAVO was launched on June 10, 2025, and had net product sales of $0.4 million for the second quarter of 2025. No SYMBRAVO sales were reported by Axsome for the comparable period in 2024 reflecting the timing of the product launch.

- Total cost of revenue was $13.4 million for the second quarter of 2025. Total cost of revenue for the comparable period in 2024 was $8.1 million.

- Research and development (R&D) expenses were $49.5 million for the second quarter of 2025, compared to $49.9 million for the comparable period in 2024. The decrease was primarily related to the completion of trials for solriamfetol in ADHD and MDD and for AXS-05 in Alzheimer's disease agitation, which was partially offset by higher personnel costs.

- Selling, general, and administrative (SG&A) expenses were $130.3 million for the second quarter of 2025, compared to $103.6 million for the comparable period in 2024. The increase was primarily related to commercialization activities for AUVELITY, including the sales force expansion, and the commercial launch of SYMBRAVO.

- Net loss for the second quarter of 2025 was $48.0 million, or $(0.97) per share, compared to a net loss of $79.3 million, or $(1.67) per share, for the comparable period in 2024. The net loss in the second quarter of 2025 includes $24.6 million of stock-based compensation expense.

- Cash and cash equivalents totaled $303.0 million at June 30, 2025, compared to $315.4 million at December 31, 2024.

- Shares of common stock outstanding were 49,815,301 at June 30, 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

AUVELITY is the first and only rapid-acting oral NMDA receptor antagonist and sigma-1 receptor agonist approved in the U.S. for the treatment of major depressive disorder.

- Approximately 192,000 prescriptions were written for AUVELITY in the second quarter of 2025, representing an increase of 56% compared to the same period in 2024, and an increase of 15% compared to the first quarter of 2025.

- Payer coverage for AUVELITY in the commercial channel expanded by 28 million new covered lives as of July 1. Overall payer coverage for AUVELITY across all channels is now at approximately 83% of all lives covered, with the proportion of covered lives in the commercial and government (Medicare and Medicaid) channels at approximately 73% and 100%, respectively.

SUNOSI

SUNOSI is the first and only dopamine and norepinephrine reuptake inhibitor approved for the treatment of excessive daytime sleepiness in narcolepsy or obstructive sleep apnea.

- Approximately 50,000 prescriptions were written for SUNOSI in the U.S. in the second quarter of 2025, representing an increase of 13% compared to the same period in 2024, and an increase of 9% compared to the first quarter of 2025.

- Payer coverage for SUNOSI across all channels is at approximately 83% of all lives covered. The proportion of lives covered for SUNOSI in the commercial and government channels are approximately 95% and 60%, respectively.

SYMBRAVO

SYMBRAVO is a novel, oral, rapidly absorbed, multi-mechanistic, selective COX-2 inhibitor and 5-$HT_{1B/1D}$ agonist approved in the U.S. for the acute treatment of migraine with or without aura in adults.

- SYMBRAVO became commercially available in U.S. pharmacies on June 10, 2025. Our SYMBRAVO field force is actively engaging healthcare providers to provide comprehensive education on SYMBRAVO.

- Effective July 1, Axsome has contracted with one of the three largest group purchasing organizations (GPOs) for potential formulary coverage of SYMBRAVO. Pharmacy benefit managers and health plans under this GPO are now able to make coverage decisions for SYMBRAVO based on the contracted terms.

- Payer coverage for SYMBRAVO across all channels is currently at approximately 38% of all lives covered. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are currently approximately 26% and 56%, respectively.

- Axsome's comprehensive patient support services, through the SYMBRAVO On My Side program, are operational and performing as planned. These include the SYMBRAVO On My Side Savings Card to reduce out-of-pocket expenses for commercially insured eligible patients who qualify, educational resources and tools for patients to facilitate discussions with their healthcare providers, and HCP samples.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of innovative, late-stage, product candidates addressing 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:** Activities for the submission of the Company's supplemental New Drug Application (sNDA) for AXS-05 in AD agitation are progressing. Axsome is on track to submit the sNDA to the FDA 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 the fourth quarter of 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 excessive daytime sleepiness (EDS), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome plans to initiate a Phase 3 trial of solriamfetol in children and adolescents with ADHD in the fourth quarter of 2025.

  The Company previously announced positive topline results from the FOCUS Phase 3 trial evaluating the efficacy and safety of solriamfetol in ADHD in adults. In the trial, solriamfetol demonstrated rapid, substantial, and statistically significant improvements in ADHD symptoms and overall disease severity 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.

- **Major Depressive Disorder:** Axsome plans to initiate a Phase 3 trial of solriamfetol in MDD patients with excessive daytime sleepiness (EDS) in the fourth quarter of 2025.

  The Company previously announced topline results from the PARADIGM Phase 3 proof-of-concept trial evaluating the efficacy and safety of solriamfetol in MDD with and without 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.

- **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.

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 plans to submit an NDA to the FDA for AXS-12 for the treatment of cataplexy in narcolepsy in the fourth quarter of 2025.

  Axsome has completed three controlled Phase 2 and Phase 3 efficacy trials and a long-term safety trial. Across these trials, AXS-12 achieved the primary endpoints and rapidly and substantially reduced cataplexy attacks, improved excessive

daytime sleepiness, and improved cognitive function compared to placebo.

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:** To address the FDA's feedback in the previously disclosed Refusal to File (RTF) letter for the Company's NDA for AXS-14 for the management of fibromyalgia, Axsome plans to initiate a Phase 3, fixed-dose, 12-week trial of AXS-14 in fibromyalgia in the fourth quarter of 2025.

Corporate Updates

- In May 2025, Axsome announced that it resolved patent litigation with Hetero Labs Ltd. and certain of its affiliates (Hetero) related to Hetero's Abbreviated New Drug Application (ANDA) for a generic version of SUNOSI. The Company entered into a license and settlement agreement with Hetero, which permits Hetero 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.

- In July 2025, the Company hosted its Frontiers in Brain Health R&D Day, featuring presentations from six leading expert clinicians and key opinion leaders who discussed current indications being targeted by Axsome's late-stage pipeline and highlighted clinical data from the development programs.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-05 for Alzheimer's disease agitation, sNDA submission (3Q 2025)
  - AXS-12 for narcolepsy, NDA submission (4Q 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 (4Q 2025)
  - Phase 3 trial of solriamfetol in ADHD in pediatric patients, initiation (4Q 2025)
  - Phase 3 trial of solriamfetol in MDD with EDS, initiation (4Q 2025)
  - Phase 3 trial of AXS-14 in fibromyalgia, initiation (4Q 2025)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its second 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 Company's ability to successfully resolve any intellectual property litigation, and even if such disputes are settled, whether the applicable federal agencies will approve of such settlements; 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)

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 303,016	$ 315,353
Accounts receivable, net	198,825	142,001
Inventories, net	18,441	15,732
Prepaid and other current assets	16,338	11,978
Total current assets	536,620	485,064
Equipment, net	667	584
Right-of-use asset - operating lease	22,472	5,383
Goodwill	12,042	12,042
Intangible asset, net	43,733	46,894
Non-current inventory and other assets	24,251	18,531
Total assets	$ 639,785	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 91,628	$ 71,997
Accrued expenses and other current liabilities	170,902	147,987
Operating lease liability, current portion	337	1,835
Contingent consideration, current	9,232	8,285
Short-term borrowings	70,000	—
Total current liabilities	342,099	230,104
Contingent consideration, non-current	79,655	91,680
Loan payable, long-term	117,540	180,710
Operating lease liability, long-term	23,624	6,046
Finance lease liability, long-term	3,792	2,943
Total liabilities	566,710	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, 49,815,301 and 48,667,587 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,303,243	1,179,797
Accumulated deficit	(1,230,173)	(1,122,787)
Total stockholders' equity	73,075	57,015
Total liabilities and stockholders' equity	$ 639,785	$ 568,498

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

	Three months ended June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Product sales, net	$ 148,959	$ 86,520	$ 269,317	$ 160,616
Royalty revenue	1,083	646	2,188	1,549
Total revenues	150,042	87,166	271,505	162,165
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	13,448	8,055	23,237	14,352
Research and development	49,541	49,853	94,326	86,683
Selling, general and administrative	130,280	103,554	251,067	202,524
Loss (Gain) in fair value of contingent consideration	(8,102)	2,160	(6,590)	748
Intangible asset amortization	1,589	1,590	3,161	3,179
Total operating expenses	186,756	165,212	365,201	307,486
Loss from operations	(36,714)	(78,046)	(93,696)	(145,321)
Interest expense, net	(1,834)	(1,299)	(4,265)	(2,381)
Loss on debt extinguishment	(10,385)	—	(10,385)	—
Loss before income taxes	(48,933)	(79,345)	(108,346)	(147,702)
Income tax benefit	960	—	960	—
Net loss	$ (47,973)	$ (79,345)	$ (107,386)	$ (147,702)
Net loss per common share, basic and diluted	$ (0.97)	$ (1.67)	$ (2.18)	$ (3.11)
Weighted average common shares outstanding, basic and diluted	49,442,001	47,573,229	49,158,159	47,482,602

Investors:
Mark Jacobson
Chief Operating Officer
(212) 332-3243
mjacobson@axsome.com

Media:
Darren Opland
Director, Corporate Communications
(929) 837-1065
dopland@axsome.com

Source: Axsome Therapeutics, Inc.