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

November 3, 2025

Total 3Q 2025 net product revenue of $171.0 million, representing 63% year-over-year growth

AUVELITY® 3Q 2025 net product sales of $136.1 million, representing 69% year-over-year growth

SUNOSI® 3Q 2025 net product revenue of $32.8 million, representing 35% year-over-year growth

SYMBRAVO® 3Q 2025 net product sales of $2.1 million

sNDA for AXS-05 in Alzheimer's disease agitation submitted to the FDA

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

NEW YORK, Nov. 03, 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 third quarter of 2025 and provided a general business update.

"Axsome posted strong revenue growth in the third quarter driven by contributions from all three of our marketed products," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "Our broad development pipeline continues to advance, and we recently submitted our supplemental NDA for AXS-05 for the treatment of Alzheimer's disease agitation, a serious condition affecting millions of patients in the U.S., and a critical unmet medical need. With robust commercial performance and pipeline execution, Axsome is well positioned to continue delivering substantial and sustained growth and transformative new medicines for patients living with serious CNS disorders."

Financial Highlights

- Total net product revenue was $171.0 million for the third quarter of 2025, representing 63% year-over-year growth, and 14% sequential growth compared to the second quarter of 2025. Total net product revenue for the third quarter of 2024 was $104.8 million.
- AUVELITY net product sales were $136.1 million for the third quarter of 2025, representing 69% year-over-year growth, and 14% sequential growth compared to the second quarter of 2025. AUVELITY net product sales for the third quarter of 2024 were $80.4 million.
- SUNOSI net product revenue was $32.8 million for the third quarter of 2025, representing 35% year-over-year growth, and 9% sequential growth compared to the second quarter of 2025. SUNOSI net product revenue for the third quarter of 2025 consisted of $31.6 million in net product sales and $1.2 million in royalty revenue associated with SUNOSI sales in out-licensed territories. SUNOSI net product revenue for the third quarter of 2024 was $24.4 million, which consisted of $23.4 million in net product sales and $1.0 million in royalty revenue.
- SYMBRAVO net product sales were $2.1 million for the third quarter of 2025, the first full quarter of commercialization following its launch in June 2025.
- Total cost of revenue was $11.9 million for the third quarter of 2025. Total cost of revenue for the comparable period in 2024 was $8.4 million.
- Research and development (R&D) expenses were $40.2 million for the third quarter of 2025, compared to $45.4 million for the comparable period in 2024. The decrease was primarily related to the completion of trials for solriamfetol in ADHD and MDD, which was partially offset by higher costs related to AXS-07.
- Selling, general, and administrative (SG&A) expenses were $150.2 million for the third quarter of 2025, compared to $95.6 million for the comparable period in 2024. The increase was primarily related to commercialization activities for AUVELITY, including the sales force expansion and direct-to-consumer advertising campaign, and the commercial launch of SYMBRAVO.

- Net loss for the third quarter of 2025 was $47.2 million, or $(0.94) per share, compared to a net loss of $64.6 million, or $(1.34) per share, for the comparable period in 2024. The net loss in the third quarter of 2025 includes $23.1 million of stock-based compensation expense and a $13.2 million non-cash charge for contingent consideration.

- Cash and cash equivalents totaled $325.3 million at September 30, 2025, compared to $315.4 million at December 31, 2024.

- Shares of common stock outstanding were 50,307,834 at September 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 209,000 prescriptions were written for AUVELITY in the third quarter of 2025, representing an increase of 46% compared to the same period in 2024, and an increase of 9% compared to the second quarter of 2025.

- Payer coverage for AUVELITY across all channels is currently at approximately 85% of all lives covered. The proportions of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 75% and 100%, respectively.

- Effective August 1, 2025, Axsome contracted with a third large group purchasing organization (GPO) for potential formulary coverage of AUVELITY. Pharmacy benefit managers and health plans under this GPO are now able to make coverage decisions for AUVELITY based on the contracted terms. Axsome has now contracted with each of the three largest GPOs for AUVELITY.

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 53,000 prescriptions were written for SUNOSI in the U.S. in the third quarter of 2025, representing an increase of 12% compared to the same period in 2024, and an increase of 5% compared to the second quarter of 2025.

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

SYMBRAVO

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

- The third quarter of 2025 was the first full quarter of sales for SYMBRAVO, which became commercially available in June 2025. Approximately 5,000 prescriptions were reported for SYMBRAVO in the third quarter of 2025.

- Payer coverage for SYMBRAVO across all channels is at approximately 52% of all lives covered as of October 1. The proportions of lives covered in the commercial and government channels are approximately 48% and 56%, respectively.

- Effective August 1, 2025, Axsome has contracted with a second large group purchasing organization (GPO) 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. Axsome has now contracted with two of the three largest GPOs for SYMBRAVO.

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:** Axsome has submitted a supplemental NDA (sNDA) to the FDA for AXS-05 in Alzheimer's disease agitation. The Company plans to announce the FDA's decision on acceptance of the filing.

- **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 has completed the FOCUS Phase 3 trial evaluating the efficacy and safety of solriamfetol in adults with ADHD. In the trial, solriamfetol met the primary and key secondary endpoints and demonstrated rapid, substantial, and statistically significant reductions in ADHD symptoms and overall disease severity compared to placebo.

- **Major Depressive Disorder with Excessive Daytime Sleepiness:** Axsome plans to initiate a Phase 3 trial of solriamfetol in MDD patients with EDS in the fourth 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. 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.

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 initiate a Phase 3, fixed-dose, 12-week, placebo-controlled trial of AXS-14 in fibromyalgia in the fourth quarter of 2025.

Anticipated Milestones

- **Regulatory and Commercial:**
  - 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:**
  - 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 third 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)

	September 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 325,272	$ 315,353
Accounts receivable, net	196,507	142,001
Inventories, net	23,774	15,732
Prepaid and other current assets	19,789	11,978
Total current assets	565,342	485,064
Equipment, net	605	584
Right-of-use asset - operating lease	21,654	5,383
Goodwill	12,042	12,042
Intangible asset, net	42,126	46,894
Non-current inventory and other assets	27,481	18,531

Total assets	$ 669,250	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 54,227	$ 71,997
Accrued expenses and other current liabilities	225,632	147,987
Operating lease liability, current portion	736	1,835
Contingent consideration, current	9,695	8,285
Short-term borrowings	70,000	—
Total current liabilities	360,290	230,104
Contingent consideration, non-current	89,870	91,680
Loan payable, long-term	117,642	180,710
Operating lease liability, long-term	23,041	6,046
Finance lease liability, long-term	4,680	2,943
Total liabilities	595,523	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, 50,307,834 and 48,667,587 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,351,124	1,179,797
Accumulated deficit	(1,277,402)	(1,122,787)
Total stockholders' equity	73,727	57,015
Total liabilities and stockholders' equity	$ 669,250	$ 568,498

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

	Three months ended September 30,		Nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Product sales, net	$ 169,784	$ 103,736	$ 439,101	$ 264,352
Royalty revenue	1,208	1,026	3,396	2,575
Total revenues	170,992	104,762	442,497	266,927
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	11,912	8,437	35,149	22,789
Research and development	40,162	45,388	134,488	132,071
Selling, general and administrative	150,235	95,564	401,302	298,088
Loss in fair value of contingent consideration	13,185	16,391	6,595	17,139
Intangible asset amortization	1,607	1,606	4,768	4,785
Total operating expenses	217,101	167,386	582,302	474,872
Loss from operations	(46,109)	(62,624)	(139,805)	(207,945)
Interest expense, net	(1,120)	(1,978)	(5,385)	(4,359)
Loss on debt extinguishment	—	—	(10,385)	—
Loss before income taxes	(47,229)	(64,602)	(155,575)	(212,304)
Income tax benefit	—	—	960	—
Net loss	$ (47,229)	$ (64,602)	$ (154,615)	$ (212,304)
Net loss per common share, basic and diluted	$ (0.94)	$ (1.34)	$ (3.13)	$ (4.45)
Weighted average common shares outstanding, basic and diluted	50,021,851	48,140,519	49,449,220	47,703,508

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