Axsome Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Update

November 2, 2026

Total 3Q 2026 net product revenue of $259.7 million, representing 52% year-over-year growth

AUVELITY® 3Q 2026 net product sales of $207.6 million, representing 53% year-over-year growth

SUNOSI® 3Q 2026 net product revenue of $48.2 million, representing 47% year-over-year growth

SYMBRAVO® 3Q 2026 net product sales of $3.9 million, representing 88% year-over-year growth

SUMMIT Phase 3 trial of AXS-05 for smoking cessation initiated

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

NEW YORK, Nov. 02, 2026 (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 2026 and provided a general business update.

"Axsome delivered 52% year-over-year total revenue growth in the third quarter, surpassing a one-billion-dollar annual run rate. We expect sustained momentum driven by strong underlying demand for Auvelity in major depressive disorder, and continued acceleration of new patient initiations in Alzheimer's disease agitation," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "Our industry-leading neuroscience pipeline continued to advance, leading to multiple anticipated regulatory and clinical trial milestones in the coming quarters. Our commercial and research and development performance positions us to continue to deliver innovation targeting significant unmet needs in brain health, with the potential to improve the lives of millions of patients."

Third Quarter 2026 Financial Highlights

- Total net product revenue was $259.7 million for the third quarter of 2026, representing 52% year-over-year growth. Total net product revenue for the comparable period in 2025 was $171.0 million.
- AUVELITY net product sales were $207.6 million for the third quarter of 2026, representing 53% year-over-year growth. AUVELITY net product sales for the comparable period in 2025 were $136.1 million.
- SUNOSI net product revenue was $48.2 million for the third quarter of 2026, representing 47% year-over-year growth, which consisted of $38.5 million in net product sales, $1.2 million in royalty revenue associated with SUNOSI sales in out-licensed territories, and $8.5 million in milestone revenue. SUNOSI net product revenue for the comparable period in 2025 was $32.8 million, which consisted of $31.6 million in net product sales and $1.2 million in royalty revenue.
- SYMBRAVO net product sales were $3.9 million for the third quarter of 2026, representing 88% year-over-year growth. SYMBRAVO net product sales for the comparable period in 2025 were $2.1 million.
- Total cost of revenue was $17.8 million for the third quarter of 2026. Total cost of revenue for the comparable period in 2025 was $11.9 million.
- Research and development (R&D) expenses were $50.6 million for the third quarter of 2026, compared to $40.2 million for the comparable period in 2025. The increase primarily reflects costs for the ongoing clinical programs for solriamfetol, AXS-14, and AXS-05.
- Selling, general, and administrative (SG&A) expenses were $203.1 million for the third quarter of 2026, compared to $150.2 million for the comparable period in 2025. The increase primarily reflects commercialization activities for AUVELITY and SYMBRAVO.
- Net loss for the third quarter of 2026 was $12.9 million, or $(0.25) per share, compared to a net loss of $47.2 million, or $(0.94) per share, for the comparable period in 2025. The net loss in the third quarter of 2026 includes $26.4 million in

stock-based compensation expense.

- Cash and cash equivalents totaled $313.9 million at September 30, 2026, compared to $322.9 million at December 31, 2025.
- Shares of common stock outstanding were 52,576,839 at September 30, 2026.

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 a first-in-class oral N-methyl-D-aspartate (NMDA) receptor antagonist and sigma-1 receptor agonist approved in the U.S. for the treatment of major depressive disorder in adults, and for the treatment of agitation associated with dementia due to Alzheimer's disease.

- Approximately 302,000 total prescriptions were written for AUVELITY in the third quarter of 2026, representing year-over-year and quarter-over-quarter increases of 40% and 14%, respectively. New-to-brand prescriptions, representing new AUVELITY patient starts, increased by 44% year-over-year and 21% quarter-over-quarter.
- Third quarter AUVELITY new-to-brand and total prescriptions among patients aged 65 years and older increased by 211% and 101%, respectively, compared to the third quarter of 2025. Third quarter AUVELITY new-to-brand and total prescriptions among patients aged 65 years and older increased by 99% and 43%, respectively, compared to the second quarter of 2026.
- Payer coverage for AUVELITY across all channels is currently at approximately 89% of all lives covered. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 82% and 100%, respectively.

SUNOSI

SUNOSI is the first and only dopamine and norepinephrine reuptake inhibitor (DNRI) approved for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

- Approximately 64,400 prescriptions were written for SUNOSI in the U.S. in the third quarter of 2026, a 15% increase compared to the same period in 2025, and a 6% increase compared to the second quarter of 2026.
- Payer coverage for SUNOSI across all channels is at approximately 82% of all lives covered, including approximately 97% of commercial lives and 59% of government lives.

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.

- Approximately 25,000 prescriptions were written for SYMBRAVO in the third quarter of 2026, a 382% increase compared to the same period in 2025, and a 7% increase compared to the second quarter of 2026.
- Payer coverage for SYMBRAVO across all channels is at approximately 57% of all lives covered, including approximately 56% of commercial lives and 57% of government lives.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of multiple, innovative 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 NMDA receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for smoking cessation.

- **Smoking Cessation:** In August 2026, Axsome initiated the SUMMIT study, a Phase 3, randomized, double-blind, active- and placebo-controlled, multicenter trial to assess the efficacy and safety of AXS-05 for the treatment of smoking cessation. The Company anticipates topline results from the SUMMIT Phase 3 trial in the second half of 2027.

Solriamfetol

Solriamfetol is Axsome's 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 symptoms, binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome is conducting the FOCUS-2 and FOCUS-3 Phase 3, randomized, double-blind, placebo-controlled, multicenter trials evaluating the efficacy and safety of solriamfetol as a treatment for children and adolescents in ADHD, respectively. The Company anticipates topline results from both studies in the second half of 2027.

- **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. Target enrollment in the trial has been reached, and the Company anticipates topline results in the first quarter of 2027.

- **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 SUSTAIN in the second half of 2027.

- **Major Depressive Disorder:** Axsome is conducting the CLARITY study, a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial evaluating the efficacy and safety of solriamfetol for the treatment of MDD with EDS symptoms. The Company anticipates completion of enrollment in CLARITY in the first half of 2027.

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's NDA for AXS-12 for the treatment of cataplexy in narcolepsy is currently under review by the FDA. The PDUFA target action date is May 1, 2027.

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 is the SS-enantiomer of reboxetine.

- **Fibromyalgia:** Axsome is conducting the FORWARD study, a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial evaluating the efficacy and safety of AXS-14 for the management of fibromyalgia. The Company anticipates completion of enrollment in the FORWARD Phase 3 trial in the third quarter of 2027.

AXS-17

AXS-17 is Axsome's novel oral GABA $_{A}$ receptor α2,3 subtype-selective positive allosteric modulator (PAM) being developed for the treatment of epilepsy.

- **Epilepsy:** Axsome plans to initiate clinical trials of AXS-17 in epilepsy in the first half of 2027.

AXS-20

AXS-20 (balipodect) is Axsome's novel oral, potent, and selective phosphodiesterase 10A (PDE10A) inhibitor being developed for the treatment of schizophrenia.

- **Schizophrenia:** Axsome plans to initiate a pivotal Phase 3 trial of AXS-20 in schizophrenia in the first half of 2027.

Anticipated Milestones

- **Clinical Trial Initiations:**

- Phase 1B trial of AXS-17 in epilepsy (1H 2027)
- Phase 3 trial of AXS-20 in schizophrenia (1H 2027)

- **Clinical Trial Topline Results:**
  - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (1Q 2027)
  - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2H 2027)
  - Phase 3 FOCUS-2 trial of solriamfetol in children with ADHD (2H 2027)
  - Phase 3 FOCUS-3 trial of solriamfetol in adolescents with ADHD (2H 2027)
  - Phase 3 SUMMIT trial of AXS-05 in smoking cessation (2H 2027)

- **Regulatory and Commercial:**
  - AXS-12 for cataplexy in narcolepsy, PDUFA target action (May 1, 2027)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its third quarter 2026 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, agitation associated with dementia due to Alzheimer's disease, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, as well as multiple novel product candidates 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, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 313,859	$ 322,933
Accounts receivable, net	343,114	224,464
Inventories, net	42,579	27,938
Prepaid and other current assets	25,084	13,651
Total current assets	724,636	588,986
Equipment, net	943	562
Right-of-use asset - operating lease	18,284	20,858
Goodwill	12,042	12,042
Intangible asset, net	35,751	40,519
Non-current inventory and other assets	35,117	26,838
Total assets	$ 826,773	$ 689,805
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 96,075	$ 65,537
Accrued expenses and other current liabilities	331,756	232,853
Operating lease liability, current portion	663	434
Contingent consideration, current	11,225	10,012
Short-term borrowings	70,000	70,000
Total current liabilities	509,719	378,836
Contingent consideration, non-current	63,610	77,540
Loan payable, long-term	118,069	117,746
Operating lease liability, long-term	20,748	23,182
Finance lease liability, long-term	9,193	4,206
Total liabilities	721,339	601,510
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, 52,576,839 and 50,882,766 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively)	5	5
Additional paid-in capital	1,540,123	1,394,251
Accumulated deficit	(1,434,694)	(1,305,961)
Total stockholders' equity	105,434	88,295
Total liabilities and stockholders' equity	$ 826,773	$ 689,805

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,	
	2026	2025	2026	2025
Revenues:				
Product sales, net	$ 249,951	$ 169,784	$ 655,706	$ 439,101
Royalty revenue and milestone revenue	9,740	1,208	13,563	3,396
Total revenues	259,691	170,992	669,269	442,497
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	17,804	11,912	46,093	35,149
Research and development	50,617	40,162	149,521	134,488
Selling, general and administrative	203,111	150,235	596,244	401,302
Loss (Gain) in fair value of contingent consideration	(2,380)	13,185	(3,286)	6,595

Intangible asset amortization	1,607	1,607	4,768	4,768
Total operating expenses	270,759	217,101	793,340	582,302
Loss from operations	(11,068)	(46,109)	(124,071)	(139,805)
Interest expense, net	(1,721)	(1,120)	(4,446)	(5,385)
Loss on debt extinguishment	—	—	—	(10,385)
Loss before income taxes	(12,789)	(47,229)	(128,517)	(155,575)
Income tax benefit (expense)	(88)	—	(216)	960
Net loss	$ (12,877)	$ (47,229)	$ (128,733)	$ (154,615)
Net loss per common share, basic and diluted	$ (0.25)	$ (0.94)	$ (2.48)	$ (3.13)
Weighted average common shares outstanding, basic and diluted	52,445,193	50,021,851	51,818,984	49,449,220

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