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

August 10, 2026

Total 2Q 2026 net product revenue of $218.4 million, representing 46% year-over-year growth

AUVELITY® 2Q 2026 net product sales of $180.3 million, representing 51% year-over-year growth

SUNOSI® 2Q 2026 net product revenue of $35.8 million, representing 20% year-over-year growth

SYMBRAVO® 2Q 2026 net product sales of $2.3 million

AUVELITY launched for treatment of agitation associated with dementia due to Alzheimer's disease in June 2026

NDA submission for AXS-12 for cataplexy in narcolepsy accepted by the FDA with PDUFA target action date of May 1, 2027

FOCUS-2 and FOCUS-3 Phase 3 trials of solriamfetol in children and adolescents with ADHD initiated

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

NEW YORK, Aug. 10, 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 second quarter of 2026 and provided a general business update.

"The second quarter was highly productive for Axsome. Our commercial business grew robustly, driven by strong underlying demand for our products, and we made important regulatory and clinical progress across our innovative neuroscience pipeline," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "We expect our commercial momentum to build over the balance of the year, in particular with anticipated continued Auvelity growth in Alzheimer's disease agitation and major depressive disorder. With a focus on commercial execution and advancement of our broad late-stage neuroscience pipeline targeting high unmet needs, novel indications, first-in-class mechanisms of action, and best-in-class product profiles, Axsome is well positioned to deliver substantial value to patients and shareholders."

Second Quarter 2026 Financial Highlights

- Total net product revenue was $218.4 million for the second quarter of 2026, representing 46% year-over-year growth. Total net product revenue for the comparable period in 2025 was $150.0 million.
- AUVELITY net product sales were $180.3 million for the second quarter of 2026, representing 51% year-over-year growth. AUVELITY net product sales for the comparable period in 2025 were $119.6 million.
- SUNOSI net product revenue was $35.8 million for the second quarter of 2026, representing 20% year-over-year growth, which consisted of $33.8 million in net product sales, $1.5 million in royalty revenue associated with SUNOSI sales in out-licensed territories, and $0.5 million in milestone revenue. SUNOSI net product revenue for the comparable period in 2025 was $30.0 million, which consisted of $28.9 million in net product sales and $1.1 million in royalty revenue.
- SYMBRAVO net product sales were $2.3 million for the second quarter of 2026, representing 461% year-over-year growth. SYMBRAVO was launched in June 2025 and had net product sales of $0.4 million for the second quarter of 2025.
- Total cost of revenue was $13.6 million for the second quarter of 2026. Total cost of revenue for the comparable period in 2025 was $13.4 million.
- Research and development (R&D) expenses were $46.2 million for the second quarter of 2026, compared to $49.5 million for the comparable period in 2025. The decrease primarily reflects lower costs for AXS-05 and AXS-14.
- Selling, general, and administrative (SG&A) expenses were $208.1 million for the second quarter of 2026, compared to $130.3 million for the comparable period in 2025. The increase primarily reflects commercialization activities for AUVELITY, including the sales force expansion and launch activities for the Alzheimer's disease agitation indication, and commercialization activities for SYMBRAVO.
- Net loss for the second quarter of 2026 was $51.3 million, or $(0.99) per share, compared to a net loss of $48.0 million, or $(0.97) per share, for the comparable period in 2025. The net loss in the second quarter of 2026 includes $27.1 million in stock-based compensation expense.
- Cash and cash equivalents totaled $319.9 million at June 30, 2026, compared to $322.9 million at December 31, 2025.

- Shares of common stock outstanding were 52,299,889 at June 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 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.

- Axsome launched AUVELITY in Alzheimer's disease agitation in June 2026.
- New-to-brand prescriptions, representing new AUVELITY patient starts, increased 126% among patients ≥65 years of age during the first eight weeks following the Alzheimer's disease agitation launch compared to the same period in the prior quarter. New-to-brand prescriptions are considered a leading indicator of growth, reflecting expanding adoption in this patient segment. These early trends have been accompanied by positive prescriber feedback and recognition of AUVELITY's differentiated profile in Alzheimer's disease agitation.
- Overall new-to-brand prescriptions in the second quarter of 2026 increased 26% compared to the first quarter of 2026, reflecting the early impact of the sales force expansion which was completed in the second quarter. Approximately 266,000 total prescriptions were written for AUVELITY in the second quarter of 2026, representing year-over-year and quarter-over-quarter increases of 34% and 12%, respectively.
- 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 DNRI approved for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

- Approximately 61,000 prescriptions were written for SUNOSI in the U.S. in the second quarter of 2026, a 14% increase compared to the same period in 2025, and an 8% increase compared to the first quarter of 2026.
- Payer coverage for SUNOSI across all channels is at approximately 82% of all lives covered, including approximately 96% 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 23,500 prescriptions were written for SYMBRAVO in the second quarter of 2026, a 30% increase compared to the first 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.
- The previously announced expansion of the SYMBRAVO sales force is substantially complete. Our expanded sales team of approximately 150 sales representatives will enable broader reach within the primary care market and deeper engagement with headache specialists and neurologists nationwide.

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 N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for smoking cessation.

- **Smoking Cessation:** Axsome is on track to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in the third quarter of 2026.

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 symptoms, binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** In June and July 2026, Axsome initiated the FOCUS-3 and FOCUS-2 Phase 3, randomized, double-blind, placebo-controlled, multicenter trials evaluating the efficacy and safety of solriamfetol as a treatment for adolescents and children with ADHD, respectively. The primary endpoint in both studies is the change from baseline to week 6 in the ADHD Rating Scale (ADHD-RS-5) total score.
- **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.
- **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 the fourth quarter of 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 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 submission for AXS-12 for the treatment of cataplexy in narcolepsy was accepted by the FDA and assigned a PDUFA target action date of 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.

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:** Phase 2 trial-enabling activities for AXS-17 in epilepsy are underway.

AXS-20

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

- **Schizophrenia:** Phase 3 trial-enabling activities for AXS-20 in schizophrenia are underway.
- **Tourette Syndrome:** Axsome plans to evaluate AXS-20 as a potential treatment for Tourette syndrome.

Anticipated Milestones

- **Clinical Trial Initiations and Progress:**
  - Phase 2/3 trial of AXS-05 in smoking cessation, initiation (3Q 2026)
- **Clinical Trial Topline Results:**
  - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (4Q 2026)
  - Phase 3 SUSTAIN trial of solriamfetol in shift work disorder (2027)

- **Regulatory and Commercial:**
  - AXS-12 for 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 second 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)

	June 30, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 319,850	$ 322,933
Accounts receivable, net	277,459	224,464
Inventories, net	37,883	27,938
Prepaid and other current assets	21,377	13,651
Total current assets	656,569	588,986

Equipment, net	874	562
Right-of-use asset - operating lease	19,157	20,858
Goodwill	12,042	12,042
Intangible asset, net	37,358	40,519
Non-current inventory and other assets	35,447	26,838
Total assets	$ 761,447	$ 689,805
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 78,969	$ 65,537
Accrued expenses and other current liabilities	299,632	232,853
Operating lease liability, current portion	646	434
Contingent consideration, current	11,199	10,012
Short-term borrowings	70,000	70,000
Total current liabilities	460,446	378,836
Contingent consideration, non-current	69,135	77,540
Loan payable, long-term	117,958	117,746
Operating lease liability, long-term	21,574	23,182
Finance lease liability, long-term	9,030	4,206
Total liabilities	678,143	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, 52,299,889 and 50,882,766 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively)	5	5
Additional paid-in capital	1,505,116	1,394,251
Accumulated deficit	(1,421,817)	(1,305,961)
Total stockholders' equity	83,304	88,295
Total liabilities and stockholders' equity	$ 761,447	$ 689,805

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,	
	2026	**2025**	**2026**	**2025**
Revenues:				
Product sales, net	$ 216,355	$ 148,959	$ 405,755	$ 269,317
Royalty revenue and milestone revenue	2,020	1,083	3,823	2,188
Total revenues	218,375	150,042	409,578	271,505
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	13,564	13,448	28,289	23,237
Research and development	46,227	49,541	98,904	94,326
Selling, general and administrative	208,137	130,280	393,133	251,067
Gain in fair value of contingent consideration	(1,496)	(8,102)	(906)	(6,590)
Intangible asset amortization	1,589	1,589	3,161	3,161
Total operating expenses	268,021	186,756	522,581	365,201
Loss from operations	(49,646)	(36,714)	(113,003)	(93,696)
Interest expense, net	(1,540)	(1,834)	(2,725)	(4,265)
Loss on debt extinguishment	—	(10,385)	—	(10,385)
Loss before income taxes	(51,186)	(48,933)	(115,728)	(108,346)
Income tax benefit (expense)	(128)	960	(128)	960
Net loss	$ (51,314)	$ (47,973)	$ (115,856)	$ (107,386)
Net loss per common share, basic and diluted	$ (0.99)	$ (0.97)	$ (2.25)	$ (2.18)
Weighted average common shares outstanding, basic and diluted	51,799,708	49,442,001	51,500,690	49,158,159

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