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

May 4, 2026

Total 1Q 2026 net product revenue of $191.2 million, representing 57% year-over-year growth

AUVELITY® 1Q 2026 net product sales of $153.2 million, representing 59% year-over-year growth

SUNOSI® 1Q 2026 net product revenue of $33.9 million, representing 34% year-over-year growth

SYMBRAVO® 1Q 2026 net product sales of $4.1 million

AUVELITY approved for the treatment of agitation associated with dementia due to Alzheimer's disease

NDA for AXS-12 for the treatment of cataplexy in narcolepsy submitted to the FDA

AXS-20 (balipodect), potentially first-in-class, pre-Phase 3, PDE10A inhibitor for schizophrenia and Tourette syndrome, added to pipeline

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

NEW YORK, May 04, 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 first quarter of 2026 and provided a general business update.

"Axsome had a tremendous start to 2026. Our commercial business delivered robust year-over-year growth in the first quarter, Auvelity was approved by the FDA as a first-in-class medicine for the treatment of agitation associated with dementia due to Alzheimer's disease, and we added a potentially first-in-class Phase 3-ready PDE10A inhibitor for schizophrenia and Tourette syndrome to our pipeline," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "The approval of Auvelity for Alzheimer's disease agitation highlights our research and development productivity, and commitment to deliver innovation to patients living with serious brain health disorders. With three differentiated marketed medicines now approved for four highly prevalent CNS conditions, and an innovative pipeline which includes six potentially first-in-class and best-in-class product candidates targeting ten conditions with significant unmet medical need in psychiatry and neurology, Axsome is positioned to advance the frontiers of brain health for patients, and deliver substantial value for shareholders."

First Quarter 2026 Financial Highlights

- Total net product revenue was $191.2 million for the first quarter of 2026, representing 57% year-over-year growth. Total net product revenue for the comparable period in 2025 was $121.5 million.
- AUVELITY net product revenue was $153.2 million for the first quarter of 2026, representing 59% year-over-year growth. AUVELITY net product sales for the comparable period in 2025 were $96.2 million.
- SUNOSI net product revenue was $33.9 million for the first quarter of 2026, representing 34% year-over-year growth, which consisted of $32.6 million in net product sales and $1.3 million in royalty revenue associated with SUNOSI sales in out-licensed territories. SUNOSI net product revenue for the comparable period in 2025 was $25.2 million, which consisted of $24.1 million in net product sales and $1.1 million in royalty revenue.
- SYMBRAVO net product revenue was $4.1 million for the first quarter of 2026.
- Total cost of revenue was $14.7 million for the first quarter of 2026. Total cost of revenue for the comparable period in 2025 was $9.8 million.
- Research and development (R&D) expenses were $52.7 million for the first quarter of 2026, compared to $44.8 million for the comparable period in 2025. The increase primarily reflects a one-time acquisition-related expense.
- Selling, general, and administrative (SG&A) expenses were $185.0 million for the first quarter of 2026, compared to $120.8 million for the comparable period in 2025. The increase primarily reflects the acceleration of pre-launch activities for AUVELITY for the Alzheimer's disease agitation indication and commercialization activities for AUVELITY, including direct-

to-consumer advertising, and commercialization activities for SYMBRAVO.

- Net loss for the first quarter of 2026 was $64.5 million, or $(1.26) per share, compared to a net loss of $59.4 million, or $(1.22) per share, for the comparable period in 2025. The net loss in the first quarter of 2026 includes $23.4 million in stock-based compensation expense.

- Cash and cash equivalents totaled $305.1 million at March 31, 2026, compared to $322.9 million at December 31, 2025.

- Shares of common stock outstanding were 51,420,445 at March 31, 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.

- Approximately 223,000 prescriptions were written for AUVELITY in the first quarter of 2026, a 35% increase compared to the first quarter of 2025, with prescriptions consistent with the fourth quarter of 2025.

- Payer coverage for AUVELITY across all channels is currently at approximately 86% of all lives. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 78% and 100%, respectively.

- In April 2026, the U.S. Food and Drug Administration (FDA) approved AUVELITY for the treatment of agitation associated with dementia due to Alzheimer's disease. AUVELITY is a first-in-class pharmacotherapy that targets the NMDA and sigma-1 receptors, which are thought to modulate key neurotransmitters implicated in Alzheimer's disease. The commercial launch of AUVELITY in Alzheimer's disease agitation is on track for June 2026.

- The recently announced expansion of the AUVELITY sales force is substantially complete. Our expanded sales team of approximately 630 sales representatives will engage a broad group of prescribers, including primary care providers, psychiatrists, neurologists, and geriatric specialists, leveraging strong and growing demand in MDD and the substantial opportunity in Alzheimer's disease agitation.

SUNOSI

SUNOSI is the first and only DNRI approved for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea or narcolepsy.

- Approximately 54,000 prescriptions were written for SUNOSI in the U.S. in the first quarter of 2026, representing an increase of 16% compared to the same period in 2025, with prescriptions consistent with the fourth quarter of 2025.

- Payer coverage for SUNOSI across all channels is approximately 83% of all covered lives. The proportion of lives covered in the commercial and government channels are approximately 96% 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.

- Approximately 17,000 prescriptions were written for SYMBRAVO in the first quarter of 2026, representing a 36% increase compared to the fourth quarter of 2025.

- Payer coverage for SYMBRAVO in the commercial channel expanded by 17 million new covered lives, effective May 2026. Overall payer coverage for SYMBRAVO across all channels is now at approximately 57% of all lives, with the proportion of covered lives in the commercial and government channels at approximately 56% and 57%, respectively.

- Based on SYMBRAVO's growth since launch and increased demand, Axsome is expanding the SYMBRAVO sales force from 100 to 150 representatives. The expansion will support broader reach within the primary care market while deepening engagement with headache specialists and neurologists nationwide.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of multiple, innovative, late-stage, 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 second 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:** Axsome is on track to initiate two pediatric Phase 3 trials of solriamfetol in ADHD, one in children and one in adolescents, in the second quarter of 2026.
- **Major Depressive Disorder:** In February 2026, Axsome initiated 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 primary endpoint is the time from randomization into the double-blind treatment period to relapse of depressive 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 second half 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 has submitted an NDA to the FDA for AXS-12 for the treatment of cataplexy in narcolepsy. The Company plans to announce the FDA's decision on acceptance of the filing.

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 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. The Company acquired balipodect in April 2026.

- **Schizophrenia:** Phase 3 trial-enabling activities for AXS-20 in schizophrenia are anticipated in 2026.
- **Tourette Syndrome:** Axsome plans to evaluate AXS-20 as a potential treatment for Tourette syndrome.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AUVELITY for Alzheimer's disease agitation, full commercial launch (June 2026)

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

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its first 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, 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)

	March 31, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 305,106	$ 322,933

Accounts receivable, net	251,062	224,464
Inventories, net	31,515	27,938
Prepaid and other current assets	23,523	13,651
Total current assets	611,206	588,986
Equipment, net	567	562
Right-of-use asset - operating lease	20,014	20,858
Goodwill	12,042	12,042
Intangible asset, net	38,947	40,519
Non-current inventory and other assets	30,831	26,838
Total assets	$ 713,607	$ 689,805
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 106,702	$ 65,537
Accrued expenses and other current liabilities	250,731	232,853
Operating lease liability, current portion	628	434
Contingent consideration, current	11,150	10,012
Short-term borrowings	70,000	70,000
Total current liabilities	439,211	378,836
Contingent consideration, non-current	73,730	77,540
Loan payable, long-term	117,850	117,746
Operating lease liability, long-term	22,385	23,182
Finance lease liability, long-term	5,844	4,206
Total liabilities	659,020	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, 51,420,445 and 50,882,766 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively)	5	5
Additional paid-in capital	1,425,085	1,394,251
Accumulated deficit	(1,370,503)	(1,305,961)
Total stockholders' equity	54,587	88,295
Total liabilities and stockholders' equity	$ 713,607	$ 689,805

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

	Three months ended March 31,	
	2026	**2025**
Revenues:		
Product sales, net	$ 189,400	$ 120,358
Royalty revenue and milestone revenue	1,803	1,105
Total revenues	191,203	121,463
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	14,725	9,789
Research and development	52,677	44,785
Selling, general and administrative	184,996	120,787
Loss in fair value of contingent consideration	590	1,512
Intangible asset amortization	1,572	1,572
Total operating expenses	254,560	178,445
Loss from operations	(63,357)	(56,982)
Interest expense, net	(1,185)	(2,431)
Loss before income taxes	(64,542)	(59,413)
Income tax expense	—	—
Net loss	$ (64,542)	$ (59,413)
Net loss per common share, basic and diluted	$ (1.26)	$ (1.22)
Weighted average common shares outstanding, basic and diluted	51,198,349	48,871,163

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