UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 23, 2026

Axsome Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37635**	**45-4241907**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One World Trade Center, 29th Floor New York, New York	**10007**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (212) 332-3241

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	AXSM	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 23, 2026, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2025 and provided an update on the Company's operations. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 23, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Axsome Therapeutics, Inc.

Date: February 23, 2026

By: /s/ Herriot Tabuteau, M.D.
Name: Herriot Tabuteau, M.D.
Title: President and Chief Executive Officer

Exhibit 99.1

Axsome Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

Total 4Q and full year 2025 net product revenue of $196.0 million and $638.5 million, respectively, representing 65% and 66% year-over-year growth

AUVELITY® 4Q and full year 2025 net product sales of $155.1 million and $507.1 million, respectively, representing 68% and 74% year-over-year growth

SUNOSI® 4Q and full year 2025 net product revenue of $36.7 million and $124.8 million, respectively, representing 40% and 32% year-over-year growth

SYMBRAVO® 4Q and full year 2025 net product sales of $4.1 million and $6.6 million, respectively

sNDA for AXS-05 for the treatment of Alzheimer's disease agitation granted Priority Review with PDUFA target action date of April 30, 2026

Acquired AXS-17, a novel oral $GABA_A$ α2,3 receptor positive allosteric modulator

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

NEW YORK, February 23, 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 fourth quarter and full year 2025 and provided a general business update.

"Our fourth quarter and full year 2025 results demonstrate strong commercial momentum across our marketed products, and advancement and expansion of our innovative CNS pipeline, which now includes five differentiated product candidates," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "2026 promises to be another eventful year for Axsome with continued commercial execution, and multiple regulatory and clinical milestones including potential FDA action on our sNDA for AXS-05 in Alzheimer's disease agitation, NDA filing for AXS-12 in narcolepsy, and clinical trial progress across our development portfolio."

Fourth Quarter and Full Year 2025 Financial Highlights

- Total net product revenue was $196.0 million for the fourth quarter 2025 and $638.5 million for the full year 2025, representing 65% and 66% year-over-year growth. Total net product revenue for the comparable periods in 2024 were $118.8 million and $385.7 million, respectively. The increase was driven by strong growth of AUVELITY and SUNOSI, and contributions from the recent launch of SYMBRAVO.
- AUVELITY net product sales were $155.1 million for the fourth quarter 2025 and $507.1 million for the full year 2025, representing 68% and 74% year-over-year growth, in the third full year of commercial launch. AUVELITY net product sales for the comparable periods in 2024 were $92.6 million and $291.4 million, respectively.
- SUNOSI net product revenue was $36.7 million for the fourth quarter 2025 and $124.8 million for the full year 2025, representing 40% and 32% year-over-year growth. SUNOSI revenue for the fourth quarter consisted of $35.4 million in net product sales and $1.3 million in royalty revenue from sales in out-licensed territories. SUNOSI revenue for the year consisted of $120.1 million in net product sales and $4.7 million in royalty revenue from sales in out-licensed territories. SUNOSI net product revenues for the comparable periods in 2024 were $26.2 million and $94.3 million, respectively, which consisted of $24.7 million and $90.3 million in net product sales.

- SYMBRAVO net product sales were $4.1 million for the fourth quarter 2025 and $6.6 million for the full year 2025.
- Total cost of revenue was $12.3 million for the fourth quarter 2025 and $47.5 million for the full year 2025, compared to $10.5 million and $33.3 million for the fourth quarter and full year 2024.
- Research and development (R&D) expenses were $48.8 million for the fourth quarter 2025 and $183.3 million for the full year 2025, compared to $55.0 million and $187.1 million for the fourth quarter and full year 2024. The decrease for the year primarily reflects the completion of clinical trials for AXS-05 in Alzheimer's disease agitation and for solriamfetol in ADHD and MDD, partially offset by one-time acquisition-related expenses and higher costs related to AXS-07.
- Selling, general, and administrative (SG&A) expenses were $169.3 million for the fourth quarter 2025 and $570.6 million for the full year 2025, compared to $113.3 million and $411.4 million for the fourth quarter and full year 2024. The increase for the year primarily reflects commercialization activities for AUVELITY, including the sales force expansion and the national launch of our direct-to-consumer advertising campaign, and the commercial launch of SYMBRAVO.
- Net loss was $28.6 million, or $(0.56) per share, for the fourth quarter 2025 and $183.2 million, or $(3.68) per share, for the full year 2025, compared to a net loss of $74.9 million, or $(1.54) per share, for the fourth quarter 2024 and $287.2 million, or $(5.99) per share, for the full year 2024. Net loss for the fourth quarter 2025 includes $22.7 million in stock-based compensation expense compared to $22.0 million in stock-based compensation expense for the fourth quarter 2024. Net loss for the full year 2025 includes $93.8 million in stock-based compensation expense, compared to $85.2 million in stock-based compensation expense for the full year 2024.
- Cash and cash equivalents totaled $322.9 million at December 31, 2025, compared to $315.4 million at December 31, 2024.
- Shares of common stock outstanding were 50,882,766 at December 31, 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 225,000 prescriptions were written for AUVELITY in the fourth quarter, a 42% increase compared to the fourth quarter of 2024, and an 8% increase compared to the third 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 response to strong and growing demand in MDD and to support the potential approval and launch of AUVELITY in Alzheimer's disease agitation, Axsome recently initiated an expansion of the AUVELITY sales force to approximately 600 sales representatives. The expansion is expected to complete in the second quarter of 2026.

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 fourth quarter, an 11% increase compared to the fourth quarter of 2024, and a 3% increase compared to the third quarter of 2025.
- Payer coverage for SUNOSI across all channels is currently at approximately 82% of all 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 13,000 prescriptions were written for SYMBRAVO in the fourth quarter of 2025, representing a 147% increase compared to the third quarter of 2025.
- Payer coverage for SYMBRAVO across all channels is currently at approximately 52% of all lives. The proportion of lives covered in the commercial and government channels are approximately 49% and 57%, respectively.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline of multiple, innovative, patent-protected 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.

- **Alzheimer's Disease Agitation:** Axsome's sNDA for AXS-05 for the treatment of Alzheimer's disease agitation was accepted for filing and granted Priority Review designation by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2026. AXS-05 was previously granted FDA Breakthrough Therapy designation for AD agitation.
- **Smoking Cessation:** Axsome plans 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 excessive daytime sleepiness (EDS) symptoms, binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome plans to conduct two pediatric Phase 3 trials of solriamfetol, one in children and one in adolescents, following a recent Type B meeting with the FDA. The Company plans to initiate both trials in the first half of 2026.

- **Major Depressive Disorder with Excessive Daytime Sleepiness symptoms:** Axsome is on track to initiate a Phase 3 trial of solriamfetol in MDD patients with EDS symptoms in the first quarter of 2026.

- **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. Based on current enrollment trends, 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.

- **Narcolepsy:** In December 2025, Axsome received formal pre-NDA meeting minutes from the FDA supporting an NDA submission for AXS-12 in narcolepsy. The Company is on track to submit the NDA this quarter. AXS-12 has been granted FDA Orphan Drug designation for narcolepsy.

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:** In January 2026, Axsome initiated the FORWARD study, a Phase 3, double-blind, placebo-controlled, randomized withdrawal trial evaluating the efficacy and safety of AXS-14 for the management of fibromyalgia. This trial will complement the previously completed parallel-group Phase 2 and Phase 3 trials, both of which met their primary endpoints.

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:** In November 2025, Axsome acquired AZD7325, now designated AXS-17. The Company has initiated tech transfer activities and Phase 2 trial-enabling activities.

Corporate Updates

- In February 2026, Axsome announced that it resolved patent litigation with Alkem Laboratories Ltd. related to Alkem's Abbreviated New Drug Application (ANDA) for a generic version of SUNOSI. The Company entered into a license and settlement agreement with Alkem, which permits Alkem 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.

Anticipated Milestones

- **Regulatory and Commercial:**
    - AXS-12 for narcolepsy, NDA submission (1Q 2026)
    - AXS-05 for Alzheimer's disease agitation, PDUFA target action (April 30, 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:**
    - Phase 3 trial of solriamfetol in MDD with EDS symptoms, initiation (1Q 2026)
    - Pivotal Phase 2/3 trial of AXS-05 in smoking cessation, initiation (2Q 2026)
    - Phase 3 trial of solriamfetol in children with ADHD, initiation (1H 2026)
    - Phase 3 trial of solriamfetol in adolescents with ADHD, initiation (1H 2026)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its fourth quarter and full year 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
(Unaudited, in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 322,933	$ 315,353
Accounts receivable, net	224,464	142,001
Inventories, net	27,938	15,732
Prepaid and other current assets	13,651	11,978
Total current assets	588,986	485,064
Equipment, net	562	584
Right-of-use asset - operating lease	20,858	5,383
Goodwill	12,042	12,042
Intangible asset, net	40,519	46,894
Non-current inventory and other assets	26,838	18,531
Total assets	$ 689,805	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 65,537	$ 71,997
Accrued expenses and other current liabilities	232,853	147,987
Operating lease liability, current portion	434	1,835
Contingent consideration, current	10,012	8,285
Short-term borrowings	70,000	—
Total current liabilities	378,836	230,104
Contingent consideration, non-current	77,540	91,680
Loan payable, long-term	117,746	180,710
Operating lease liability, long-term	23,182	6,046
Finance lease liability, long-term	4,206	2,943
Total liabilities	601,510	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, 50,882,766 and 48,667,587 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,394,251	1,179,797
Accumulated deficit	(1,305,961)	(1,122,787)
Total stockholders' equity	88,295	57,015
Total liabilities and stockholders' equity	$ 689,805	$ 568,498

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

	Three months ended December 31,		Year ended December 31,	
	2025	2024	2025	2024
Revenues:				
Product sales, net	$ 194,695	$ 117,325	$ 633,796	$ 381,677
Royalty revenue and milestone revenue	1,304	1,441	4,700	4,016
Total revenues	195,999	118,766	638,496	385,693
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	12,329	10,514	47,478	33,303
Research and development	48,791	55,006	183,279	187,077
Selling, general and administrative	169,297	113,271	570,599	411,359
Loss (Gain) in fair value of contingent consideration	(9,068)	10,985	(2,473)	28,124
Intangible asset amortization	1,607	1,607	6,375	6,392
Total operating expenses	222,956	191,383	805,258	666,255
Loss from operations	(26,957)	(72,617)	(166,762)	(280,562)
Interest expense, net	(1,172)	(2,210)	(6,557)	(6,569)
Loss on debt extinguishment	—	—	(10,385)	—
Loss before income taxes	(28,129)	(74,827)	(183,704)	(287,131)
Income tax benefit (expense)	(430)	(85)	530	(85)
Net loss	$ (28,559)	$ (74,912)	$ (183,174)	$ (287,216)
Net loss per common share, basic and diluted	$ (0.56)	$ (1.54)	$ (3.68)	$ (5.99)
Weighted average common shares outstanding, basic and diluted	50,631,337	48,541,905	49,747,178	47,914,253

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