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): December 31, 2025

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 8.01 Other Events.

On December 31, 2025, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration's acceptance and grant of Priority Review for its supplemental New Drug Application for the treatment of Alzheimer's Disease Agitation.

Also on December 31, 2025, the Company issued a press release announcing that it had received formal pre-New Drug Application ("NDA") meeting minutes from the FDA for its planned NDA submission for AXS-12 in narcolepsy.

The full text of each respective press release is filed as Exhibit 99.1 & Exhibit 99.2 hereto, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated December 31, 2025.
99.2	Press Release dated December 31, 2025.
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: December 31, 2025

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

Exhibit 99.1

Axsome Therapeutics Announces FDA Pre-NDA Meeting Minutes for AXS-12 in Narcolepsy Supporting NDA Submission

New Drug Application (NDA) submission on track for January 2026

NEW YORK, December 31, 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 that it has received formal pre-New Drug Application (NDA) meeting minutes from the U.S. Food and Drug Administration (FDA) supporting an NDA submission for AXS-12 in narcolepsy. AXS-12 (reboxetine) is a highly selective and potent norepinephrine reuptake inhibitor and cortical dopamine modulator. The purpose of the meeting was to reach agreement with the FDA on the proposed content and format of the Company's planned NDA submission including the clinical and nonclinical requirements.

Based on the feedback from the FDA, the Company's regulatory data package would be sufficient for the submission of an NDA for AXS-12 for the treatment of cataplexy in narcolepsy. Axsome anticipates completing the NDA submission in January 2026. Acceptance of the final NDA will be subject to the FDA's review of the complete filing.

"We are pleased with the FDA pre-NDA meeting minutes which allow completion of the NDA submission for AXS-12 for the treatment of cataplexy in patients with narcolepsy shortly in January 2026," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We are excited by the potential of AXS-12 to provide a new, differentiated treatment option to patients living with this debilitating condition, if approved."

AXS-12's clinical development program in narcolepsy includes three controlled efficacy trials, and a completed long-term safety trial.

AXS-12 has been granted Orphan Drug Designation for the treatment of narcolepsy. Orphan Drug Designation is granted to promising drugs intended for the safe and effective treatment of rare diseases, defined as those affecting fewer than 200,000 people in the U.S. This designation may entitle Axsome to a period of seven years of marketing exclusivity in the U.S. upon FDA approval and a waiver of the Company's obligation to pay the FDA application user fees for the product as required by the Prescription Drug User Fee Act.

About Narcolepsy

Narcolepsy is a serious and debilitating orphan neurological condition that causes dysregulation of the sleep-wake cycle and is characterized clinically by excessive daytime sleepiness, cataplexy, hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep.[1-3] Cataplexy is seen in an estimated 70% of narcolepsy patients and is a sudden reduction or loss of muscle tone while a patient is awake, typically triggered by strong emotions such as laughter, fear, anger, stress, or excitement.[4-5] Narcolepsy is a life-long condition that interferes with cognitive, psychological, and social functioning, increases the risk of work- and driving-related accidents, and is associated with a 1.5-fold higher mortality rate.[6-8]

About AXS-12

AXS-12 (reboxetine) is a highly selective and potent norepinephrine reuptake inhibitor and cortical dopamine modulator under development for the treatment of narcolepsy. AXS-12 is thought to modulate noradrenergic activity to promote maintain tone during wakefulness, and noradrenergic and cortical dopamine signaling to promote wakefulness and enhance cognition. AXS-12 has been granted U.S. Food and Drug Administration (FDA) Orphan Drug Designation for the treatment of narcolepsy. AXS-12 is covered by issued patents providing protection to at least 2039. AXS-12 is an investigational drug product not approved by the FDA.

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 the Company's website at www.axsome.com.

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 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 circumstance.

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References

1. American Academy of Sleep Medicine. The International Classification of Sleep Disorders. Third Edition (ICSD-3). 2014.
2. National Institute of Neurological Disorders and Stroke. Narcolepsy.https://www.ninds.nih.gov/health-information/disorders/narcolepsy. Accessed September 2024.
3. España RA, Scammell TE. Sleep neurobiology from a clinical perspective. Sleep. 2011 Jul 1;34(7):845-58.
4. Narcolepsy Network. About Narcolepsy. https://narcolepsynetwork.org/about-narcolepsy/. Accessed September 2024.
5. Swick TJ. Treatment paradigms for cataplexy in narcolepsy: past, present, and future. Nat Sci Sleep. 2015 Dec 11;7:159-69.
6. Tadrous R, O'Rourke D, Mockler D, Broderick J. Health-related quality of life in narcolepsy: A systematic review and meta-analysis. J Sleep Res. 2021 Dec;30(6):e13383.
7. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea With Positive Airway Pressure: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. J Clin Sleep Med. 2019 Feb 15;15(2):301-334.
8. Ohayon MM, Black J, Lai C, Eller M, Guinta D, Bhattacharyya A. Increased mortality in narcolepsy. Sleep. 2014 Mar 1;37(3):439-44.

Exhibit 99.2

Axsome Therapeutics Announces FDA Acceptance and Priority Review of Supplemental New Drug Application for AXS-05 for the Treatment of Alzheimer's Disease Agitation

FDA grants AXS-05 Priority Review designation and sets PDUFA action goal date of April 30, 2026

NEW YORK, December 31, 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 that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's supplemental New Drug Application (NDA) for AXS-05 (dextromethorphan HBr and bupropion HCl) for the treatment of Alzheimer's disease agitation, and has granted the application Priority Review designation. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2026.

Priority Review is granted by the FDA to applications for medicines that, if approved, would provide significant improvements in the effectiveness or safety of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. A Priority Review designation means the FDA's goal is to take action on an application within 6 months, compared to 10 months under standard review.

"We are very pleased the FDA has accepted and granted priority review to our supplemental NDA for AXS-05 for the treatment of Alzheimer's disease agitation," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Up to 76% of people with Alzheimer's disease experience agitation, representing a significant unmet medical need for patients and their caregivers, and currently there is a dearth of approved treatments. We look forward to continuing to work with the FDA for the remainder of the review."

The FDA previously granted Breakthrough Therapy designation for AXS-05 for the treatment of Alzheimer's disease agitation in June 2020. A Breakthrough Therapy designation is granted to potentially expedite development and review timelines for a promising investigational medicine when preliminary clinical evidence indicates it may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies for a serious or life-threatening condition.

The supplemental NDA is the culmination of a comprehensive clinical development program of AXS-05 in Alzheimer's disease agitation, including four randomized, double-blind, controlled Phase 3 clinical trials and a long-term safety trial.

About Alzheimer's Disease Agitation

Alzheimer's disease (AD) is the most common form of dementia, affecting approximately 7 million people in the United States.[1] Agitation is reported in up to 76% of patients with AD and is characterized by emotional distress, verbal and physical aggressiveness, disruptive irritability, and disinhibition.[1,2] AD agitation has been associated with accelerated cognitive decline, increased caregiver burden, earlier nursing home placement, and increased mortality.[3]

About AXS-05

AXS-05 (dextromethorphan-bupropion) is a novel, oral, investigational N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 agonist, and aminoketone CYP2D6 inhibitor under development for the treatment of Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 utilizes a proprietary formulation and dose of dextromethorphan and bupropion, and Axsome's metabolic inhibition technology, to modulate the delivery of the components. The dextromethorphan component of AXS-05 is an uncompetitive NMDA receptor antagonist, also known as a glutamate receptor modulator, and a sigma-1 receptor agonist. The bupropion component of AXS-05 serves to increase the bioavailability of dextromethorphan and is a norepinephrine and dopamine reuptake inhibitor. AXS-05 is covered by a robust patent estate extending out to at least 2043. AXS-05 was granted U.S. FDA Breakthrough Therapy designation for the treatment of Alzheimer's disease agitation in June 2020. AXS-05 (AUVELITY®) is approved in the U.S. for the treatment of major depressive disorder in adults. AXS-05 is not approved by the FDA for Alzheimer's disease agitation.

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.

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References

1. Alzheimer’s Association. 2025 Alzheimer’s Disease Facts and Figures.
2. Van der Mussele, S. et al. Agitation-associated behavioral symptoms in mild cognitive impairment and Alzheimer's dementia. Aging Ment Health. 2015;19(3):247-57.
3. Porsteinsson, A.P. and Antonsdottir, I.M. An update on the advancements in the treatment of agitation in Alzheimer’s disease. Expert Opin Pharmacother. 2017 Apr;18(6):611-620.