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 10, 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, 22nd 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 February 10, 2025, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing that it has entered into a settlement agreement with Teva Pharmaceuticals, Inc. (Teva) resolving all patent litigation related to Axsome's AUVELITY® (dextromethorphan HBr– bupropion HCl) product. The litigation resulted from submission by Teva of an Abbreviated New Drug Application to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of AUVELITY in the United States prior to the expiration of applicable Axsome patents. Under the terms of the settlement agreement, Axsome will grant Teva a license to sell its generic version of AUVELITY beginning on or after March 31, 2039 if pediatric exclusivity is granted for AUVELITY, or on or after September 30, 2038 if no pediatric exclusivity is granted, subject to FDA approval and conditions and exceptions customary for agreements of this type. In accordance with the agreement, the parties will terminate all ongoing litigation between Axsome and Teva regarding AUVELITY patents pending in the U.S. District Court for the District of New Jersey. The settlement agreement resolves all outstanding patent litigation relating to AUVELITY.

The settlement agreement is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The description of the settlement agreement contained herein does not purport to be complete.

The full text of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 10, 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: February 10, 2025

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

Exhibit 99.1

Axsome Therapeutics Announces Settlement Agreement Resolving AUVELITY® (dextromethorphan HBr – bupropion HCl) Patent Litigation

NEW YORK, February 10, 2025 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM) (Axsome), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced that it has entered into a settlement agreement with Teva Pharmaceuticals, Inc. (Teva) resolving all patent litigation related to Axsome's AUVELITY® (dextromethorphan HBr – bupropion HCl) product. The litigation resulted from submission by Teva of an Abbreviated New Drug Application to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of AUVELITY in the United States prior to the expiration of applicable Axsome patents.

Under the terms of the settlement agreement, Axsome will grant Teva a license to sell its generic version of AUVELITY beginning on or after March 31, 2039, if pediatric exclusivity is granted for AUVELITY, or on or after September 30, 2038, if no pediatric exclusivity is granted, subject to FDA approval and conditions and exceptions customary for agreements of this type. In accordance with the agreement, the parties will terminate all ongoing litigation between Axsome and Teva regarding AUVELITY patents pending in the U.S. District Court for the District of New Jersey.

The settlement agreement resolves all outstanding patent litigation relating to AUVELITY.

"Axsome is proud of its commitment to innovating treatments aimed at improving the lives of the millions of patients living with central nervous system disorders. The resolution of this patent litigation underscores the value of that innovation as it relates to AUVELITY, and more broadly reflects the strength of Axsome's intellectual property portfolio," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics. "With our industry-leading neuroscience pipeline addressing difficult-to-treat conditions, we look forward to continuing to serve our patient communities through innovation and delivery of differentiated new medicines."

As required by law, Axsome and Teva will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

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 and excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea 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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