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): March 25, 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 March 25, 2025, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing that its FOCUS (Forward Treatment of Attention Deficit and Hyperactivity Using Solriamfetol) Phase 3 trial of the Company's solriamfetol product in attention deficit hyperactivity disorder achieved its primary and key secondary endpoints.

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 March 25, 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: March 25, 2025

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

Exhibit 99.1

Axsome Therapeutics Announces FOCUS Phase 3 Trial of Solriamfetol in Adults with Attention Deficit Hyperactivity Disorder (ADHD) Achieves Primary Endpoint

Demonstrated substantial and statistically significant improvement in ADHD symptoms as measured by the AISRS total score compared to placebo (p=0.039, primary endpoint, 150 mg solriamfetol)

Statistically significant reduction in overall ADHD disease severity as measured by the CGI-S score compared to placebo (p=0.017, key secondary endpoint, 150 mg solriamfetol)

Statistically significant rate of clinical response on the AISRS compared to placebo (p=0.024, 150 mg solriamfetol)

Onset of action as early as Week 1 compared to placebo (p=0.036, AISRS, 150 mg solriamfetol)

Well tolerated with safety profile generally consistent with prior solriamfetol trials

NEW YORK, March 25, 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 FOCUS Phase 3 trial of solriamfetol in the treatment of attention deficit hyperactivity disorder (ADHD) achieved its primary and key secondary endpoints demonstrating statistically significant improvements in ADHD symptoms and disease severity with solriamfetol compared to placebo. The FOCUS study was a randomized, double-blind, placebo-controlled, multicenter, U.S. trial, in which 516 adults with ADHD were randomized to receive solriamfetol 150 mg, solriamfetol 300 mg, or placebo, once daily, for 6 weeks.

The study achieved the primary endpoint by demonstrating a statistically significant reduction in the Adult ADHD Investigator Symptom Report Scale (AISRS) total score compared to placebo at Week 6, with mean reductions from baseline of 17.7 points for solriamfetol 150 mg and 14.3 points for placebo (p=0.039). Overall, the improvement with solriamfetol at Week 6 represents a 45% mean reduction from baseline in ADHD symptoms. Improvements in the AISRS total score were greater with solriamfetol compared to placebo starting at Week 1 (p=0.036). Clinical response, defined as ≥30% improvement from baseline in the AISRS total score, was achieved by a statistically significantly greater percentage of patients treated with solriamfetol 150 mg (53.5%) compared to those treated with placebo (41.3%) at Week 6 (p=0.024).

The study also achieved the key secondary endpoint by statistically significantly reducing overall ADHD disease severity compared to placebo, as assessed by the Clinical Global Impression of Severity (CGI-S) for ADHD, at Week 6 (p=0.017). Results on the primary and key secondary endpoints for the exploratory 300 mg solriamfetol dose were numerically superior compared to placebo but were not statistically significant.

Gregory Mattingly, M.D., Associate Clinical Professor of Psychiatry at the Washington University School of Medicine and President of the American Professional Society for ADHD and Related Disorders, commented, “ADHD substantially impairs social, academic, and occupational functioning, while negatively impacting patient quality of life and increasing the risk of morbidity and mortality. The results of the FOCUS trial demonstrate that solriamfetol was able to reduce mean ADHD symptom burden by nearly fifty percent, which contributed to significant reductions in disease severity. These results are especially promising as part of a comprehensive wellness plan for individuals with ADHD. The symptom improvements observed with solriamfetol were accompanied by a favorable safety and tolerability profile. Based on these compelling data, solriamfetol has the potential to be an important new treatment option for adult patients living with ADHD.”

Herriot Tabuteau, MD, Chief Executive Officer of Axsome, said, “We are pleased with the positive results of the FOCUS trial which provide the first evidence from a multicenter controlled trial of the efficacy of solriamfetol in the treatment of ADHD. ADHD is a serious, heterogenous, and prevalent condition. We look forward to advancing the development of solriamfetol as a new, differentiated potential treatment for the millions of patients living ADHD. With these results in the adult population in hand, we plan to initiate a trial in pediatric patients this year.”

Solriamfetol was safe and well tolerated in the trial, with a side effect profile that was consistent with the established safety profile of solriamfetol. Rates of adverse events were dose dependent. There were no serious adverse events reported in the trial.

About the FOCUS Trial

FOCUS (Forward Treatment of Attention Deficit and Hyperactivity Using Solriamfetol) was a Phase 3, randomized, double-blind, placebo-controlled, multicenter, 6-week, parallel group trial to evaluate the efficacy and safety of solriamfetol in adults with ADHD in the United States. A total of 516 adult patients with a primary diagnosis of ADHD were randomized 1:1:1 to treatment with solriamfetol 150 mg, solriamfetol 300 mg, or placebo, once daily for 6 weeks. The primary endpoint was the change from baseline in the Adult ADHD Investigator Symptom Report Scale (AISRS) total score at Week 6. Total scores on the AISRS range from 0 to 54, with 0 corresponding to total absence of symptoms and higher scores corresponding to greater symptom severity. Mean baseline AISRS total scores for the solriamfetol 150 mg, solriamfetol 300 mg, and placebo groups were 39.1, 38.3, and 37.9 respectively. The key secondary endpoint was the change from baseline in the Clinical Global Impression of Severity (CGI-S) for ADHD at Week 6.

About Attention Deficit Hyperactivity Disorder

Attention deficit hyperactivity disorder (ADHD) is a chronic neurobiological and developmental disorder characterized by a persistent pattern of inattention, hyperactivity or impulsivity, that interferes with functioning or development.[1] Impairments in cognition are apparent in attention, planning and problem solving, working memory, and behavioral inhibition.[2,3] An estimated 15.5 million adults and 7 million children in the U.S. are affected by ADHD,[4,5] with approximately two-thirds or more of children with ADHD continuing to experience symptoms into adulthood.[6] The total annual societal excess cost associated with adult ADHD in the U.S. has been estimated at over $120 billion.[7]

About Solriamfetol

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

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.

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 circumstances.

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