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): January 30, 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 January 30, 2025, Axsome Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved SYMBRAVO® for the acute treatment of migraine with or without aura in adults.

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 January 30, 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: January 30, 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 Approval of SYMBRAVO® (meloxicam and rizatriptan) for the Acute Treatment of Migraine with or without Aura in Adults

A single oral dose of SYMBRAVO provided rapid migraine pain freedom and return to normal functioning within 2 hours, and sustained efficacy through 24 and 48 hours

85% and 77% of patients treated with a single dose of SYMBRAVO did not require migraine rescue medication within 24 hours in two Phase 3 studies

SYMBRAVO demonstrated superior efficacy across a broad range of migraine severity (mild, moderate, and severe), and in head-to-head evaluation

SYMBRAVO incorporates Axsome's rapid absorption technology and mechanisms that target multiple migraine attack pathways

Company to host conference call and webcast Friday, January 31, at 8:00 AM Eastern

NEW YORK, January 30, 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 approved SYMBRAVO® (meloxicam and rizatriptan) for the acute treatment of migraine with or without aura in adults.[1] SYMBRAVO represents a novel multi-mechanistic approach to treating migraine that targets multiple pathways underlying a migraine attack. SYMBRAVO can rapidly eliminate migraine pain and return patients to normal functioning, with efficacy sustained through 24 and 48 hours in some patients after a single dose. The efficacy of SYMBRAVO was demonstrated across a broad range of settings including at the earliest onset of migraine when the pain was mild, in patients with moderate and severe migraine pain, and in those with a history of various responses to prior acute treatments. The Company expects SYMBRAVO to be commercially available in the U.S. in approximately four months.

Richard B. Lipton, MD, Professor of Neurology and Director of the Montefiore Headache Center, Albert Einstein College of Medicine, commented, "A significant proportion of migraine patients experience inadequate efficacy with currently available acute treatments, leading to even greater suffering, and an increased risk of worsening of migraine pain and attack frequency. Results of multiple clinical trials demonstrate that SYMBRAVO can provide rapid and long-lasting freedom from migraine pain, whether treatment is taken early in the attack while the pain is mild, or later in the attack when the pain may be severe. The approval of SYMBRAVO is a long awaited and much welcomed advancement for clinicians and our patients, providing a new, meaningful treatment option."

Stewart Tepper, MD, Clinical Professor of Neurology at the Geisel School of Medicine at Dartmouth and Vice President of the New England Institute for Neurology and Headache, said, "Migraine is a debilitating condition that affects millions of Americans. Unfortunately, many patients still struggle to find an option that effectively treats their attacks and is both safe and well tolerated, which creates a great need for new migraine medicines. SYMBRAVO's approval by the FDA provides a new medicine for physicians and patients that was designed to target key unmet needs in the migraine treatment space. The clinical data supporting its approval validates the additive benefit of SYMBRAVO's multi-mechanistic design and demonstrates its potential to make a meaningful difference for the migraine community."

Susan Doughty, Executive Director of the Coalition for Headache and Migraine Patients (CHAMP), added, “Migraine is one of the most misunderstood and stigmatized neurological diseases, despite the fact that one in four households in the U.S. includes someone living with it. This widespread lack of understanding creates unnecessary barriers for individuals seeking proper diagnosis, care, and treatment. CHAMP, alongside our 20 plus dedicated coalition organizations and patient advocates, is committed to empowering the migraine community by providing education, reducing stigma, and advocating for fair and equitable access to treatment options. The approval of SYMBRAVO as a new acute treatment for migraine is an important step forward, offering a new option for people seeking relief. We also see this moment as an opportunity to continue to shine a bright light on migraine, fostering greater awareness and helping to dismantle the stigma that so often surrounds this disease.”

The FDA approval of SYMBRAVO is based on the results of the Phase 3 MOMENTUM trial that treated migraine of moderate and severe pain intensity, the Phase 3 INTERCEPT trial that treated migraine when the initial pain was mild, and the Phase 3 MOVEMENT long-term open label safety trial. In this comprehensive clinical program, over 21,000 migraine attacks were treated with SYMBRAVO.

In the MOMENTUM trial, SYMBRAVO demonstrated a statistically significantly greater percentage of patients achieving pain freedom and freedom from their most bothersome symptom (photophobia, phonophobia, nausea) 2 hours after dosing compared to placebo. SYMBRAVO also demonstrated statistical superiority for pain relief (reduction of moderate or severe pain to no pain or mild pain) and the ability to perform normal daily activities. The benefits of pain freedom at 2 hours were sustained through 24 and 48 hours for many patients. In a head-to-head comparison, SYMBRAVO demonstrated statistically significant superiority compared to rizatriptan on sustained pain freedom from 2 to 24 hours. Notably, these benefits were seen with only a single dose of SYMBRAVO. In the MOMENTUM trial, 77% of patients treated with SYMBRAVO did not require rescue medication within 24 hours post dose.

In the INTERCEPT trial, SYMBRAVO demonstrated a statistically significantly greater percentage of patients achieving pain freedom and freedom from their most bothersome symptom (photophobia, phonophobia, nausea) 2 hours after dosing compared to placebo. The benefits of pain freedom at 2 hours were sustained through 24 and 48 hours for many patients. Notably, these benefits were seen with only a single dose of SYMBRAVO. In the INTERCEPT trial, 85% of patients treated with SYMBRAVO did not require rescue medication within 24 hours post dose.

The most common adverse reactions ($\geq$1% and greater than placebo) in the controlled studies were somnolence and dizziness, being reported each in 2% and 1% of patients in the SYMBRAVO and placebo arms, respectively. The long-term safety of SYMBRAVO was demonstrated in the MOVEMENT trial, which assessed 706 patients dosing intermittently for up to 12 months and treating at least 2 migraines per month with SYMBRAVO.

SYMBRAVO is engineered with Axsome’s patented MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) rapid absorption technology. MoSEIC results in a five times faster median time to maximum plasma concentration for meloxicam while maintaining a long plasma half-life, enabling meloxicam’s use as a new molecular entity for the acute treatment of migraine. SYMBRAVO is protected by a robust patent estate extending out to at least 2040.

Herriot Tabuteau, MD, Chief Executive Officer of Axsome Therapeutics, said, “Today’s approval of SYMBRAVO marks an important milestone for the migraine community by providing a rationally designed novel acute treatment for this debilitating condition. Migraine attacks strike without warning, and disrupt the lives of estimated more than 39 million patients in the U.S. alone. SYMBRAVO provides patients and clinicians an important new option which can quickly stop a migraine attack, keep it away, and allow patients to resume their normal activities, with just a single dose. SYMBRAVO demonstrates Axsome’s commitment to developing and delivering differentiated new treatments to improve the lives of patients living with difficult to treat central nervous system disorders.”

Conference Call Information

Axsome will host a conference call and webcast on Friday, January 31, at 8:00 a.m. Eastern Time to discuss the approval of SYMBRAVO. Dr. Stewart Tepper, Clinical Professor of Neurology at the Geisel School of Medicine at Dartmouth and Vice President of the New England Institute for Neurology and Headache, will join the call and will be available to answer questions during the Q&A session. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic) or +1 (201) 389-0851 (international). A live webcast can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the webcast will be available for approximately 30 days following the live event.

About Migraine

Migraine is a serious neurological condition characterized by recurrent attacks of pulsating, often severe and disabling head pain associated with nausea, sensitivity to light, and sensitivity to sound.[2] It is estimated that over 39 million Americans suffer from migraine, and it is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation.[3-5] Extensive surveys of migraine sufferers underscore the unmet need for therapies that work faster, more consistently, and result in less symptom recurrence.[6,7] Over 70% of patients report experiencing an inadequate response to their oral, acute migraine treatment.[8]

About SYMBRAVO

SYMBRAVO is a novel, oral, single-dose medicine approved for the acute treatment of migraine with or without aura in adults. SYMBRAVO consists of MoSEIC™ meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC (Molecular Solubility Enhanced Inclusion Complex) technology, which enables the rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug (NSAID) and rizatriptan is a 5-$HT_{1B/1D}$ agonist. SYMBRAVO is designed to provide rapid, enhanced, and consistent migraine pain relief, and reduced symptom recurrence. The exact mechanism of action of SYMBRAVO in the treatment of acute migraine is unknown.

For more information, visit www.symbravo.com.

INDICATION

SYMBRAVO® (meloxicam and rizatriptan) is indicated for the acute treatment of migraine with or without aura in adults.

IMPORTANT SAFETY INFORMATION

Limitations of Use

SYMBRAVO is not indicated for the preventative treatment of migraine or for the treatment of cluster headache.

CONTRAINDICATIONS

SYMBRAVO is contraindicated in patients with:

- Ischemic coronary artery disease or other significant underlying cardiovascular disease
- Coronary artery vasospasm
- In the setting of CABG surgery
- History of stroke or transient ischemic attack

- Hemiplegic or basilar migraine
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Concomitant use of propranolol
- Recent (within 24 hours) use of an ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), another 5-HT_1 agonist (e.g., another triptan)
- Concurrent administration or recent discontinuation (i.e., within the past 2 weeks) of a MAO-A inhibitor
- Known hypersensitivity to SYMBRAVO, meloxicam, rizatriptan, NSAIDs, triptans, or any of the excipients in SYMBRAVO
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
- Moderate to severe renal insufficiency in patients who are at risk for renal failure due to volume depletion or who are on dialysis

WARNINGS AND PRECAUTIONS

- **Cardiovascular Thrombotic Events, Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina**: Perform cardiac evaluation in patients with multiple cardiovascular risk factors.
- **Arrhythmias**: Discontinue dosing if arrhythmia occurs.
- **Cerebral Hemorrhage, Subarachnoid Hemorrhage, and Stroke**: Discontinue dosing if occurs.
- **Anaphylactic Reactions**: Seek emergency help if an anaphylactic reaction occurs.
- **Chest/Throat/Neck/Jaw Pain, Tightness, Pressure, or Heaviness**: Generally not associated with myocardial ischemia; evaluate patients at high risk.
- **Gastrointestinal Ischemic Events, Peripheral Vasospastic Reactions**: Discontinue dosing if occurs.
- **Hepatotoxicity**: Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.
- **Hypertension**: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.
- **Heart Failure and Edema**: Avoid use of SYMBRAVO in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure.
- **Renal Toxicity and Hyperkalemia**: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Use is not recommended in patients with moderate to severe renal insufficiency; avoid the use in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal function.

- **Serious Skin Reactions**: Discontinue SYMBRAVO at first appearance of skin rash or other signs of hypersensitivity.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**: Discontinue SYMBRAVO and evaluate clinically.
- **Fetal Toxicity**: Limit use of NSAIDs, including SYMBRAVO, between about 20 to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus.
- **Hematologic Toxicity**: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.
- **Exacerbation of Asthma Related to Aspirin Sensitivity**: SYMBRAVO is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).
- **Medication Overuse Headache**: Detoxification may be necessary.
- **Serotonin Syndrome**: Discontinue dosing if occurs.

Most common adverse reactions (≥1% and greater than placebo): dizziness and somnolence.

Use in specific populations:

- **Infertility:** NSAIDs are associated with reversible infertility. Consider withdrawal of SYMBRAVO in women who have difficulties conceiving.

SYMBRAVO is available in 20 mg meloxicam / 10 mg rizatriptan tablets.

Please see full Prescribing Information, including **Boxed Warning** for risk of serious cardiovascular and gastrointestinal adverse events, and Medication Guide.

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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References

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