# 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**

**October 28, 2019**
Date of report (Date of earliest event reported)

# 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.) |

| **200 Broadway, 3rd Floor**<br>**New York, New York** | **10038** |
|---|---|
| (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)

**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 | The Nasdaq Global Market |

Check the appropriate box below if the Form 8-K 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))

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.**

October 28, 2019, Axsome Therapeutics, Inc. issued a press release announcing the results of the MINDSET (Migraine Treatment Needs and Physician Receptivity) survey of migraine physicians.

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 October 28, 2019. |

**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.**

Dated: October 28, 2019

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

**Axsome Therapeutics Announces Results of MINDSET Physician Survey Affirming Unmet Need and Favorable Profile of AXS-07 in the Acute Treatment of Migraine**

*Majority of physicians indicate improved efficacy is most significant unmet need in the acute treatment of migraine*

*Majority of physicians would be more likely to prescribe AXS-07 over current and other emerging treatments if AXS-07 efficacy is confirmed in ongoing MOMENTUM Phase 3 trial*

*MINDSET results confirm rationale for the ongoing MOMENTUM and INTERCEPT Phase 3 trials of AXS-07*

*Survey physicians treat in aggregate more than 50,000 migraine patients annually*

NEW YORK, October 28, 2019 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced results of the "Migraine Treatment Needs and Physician Receptivity" (MINDSET) survey, which demonstrated a significant unmet need for more efficacious acute migraine treatments and a high willingness of physicians to prescribe AXS-07 should it meet the objectives of the ongoing MOMENTUM Phase 3 trial in patients with difficult-to-treat migraines. MINDSET surveyed 106 neurologists and other migraine-treating physicians, who collectively treat more than 50,000 migraine patients annually, to understand physicians' views of the unmet needs in the acute treatment of migraine and their potential receptivity to AXS-07. AXS-07 (MoSEIC™ meloxicam/rizatriptan) is a novel, oral, investigational medicine with distinct dual mechanisms of action, currently being evaluated in two Phase 3 efficacy trials (MOMENTUM and INTERCEPT) for the acute treatment of migraine.

According to the vast majority of physicians (85%), the most significant unmet need in the acute treatment of migraine is efficacy, and the majority of their patients who switch acute migraine treatments (62%) do so because of suboptimal efficacy. Physicians would prescribe AXS-07 to 37% of their patients who experience difficult-to-treat migraine if it demonstrates efficacy over placebo in the ongoing MOMENTUM trial in patients with a history of inadequate response. If AXS-07 demonstrates superior efficacy to rizatriptan as assessed in the MOMENTUM trial, approximately 90% of physicians report they are more likely to prescribe AXS-07 over currently available treatments, and over other emerging therapies, including oral CGRPs, that have not demonstrated superiority to current therapies. More than half (56%) of physicians report that they are significantly or moderately more likely to prescribe AXS-07 over these other treatments. Results of the survey also indicate that treating physicians are significantly concerned that suboptimal response to acute migraine treatments may lead to progression to chronic migraine. Furthermore, the majority of physicians believe it is very important to administer acute treatments at the earliest sign of migraine pain.

"Migraine causes people to lose their jobs, lose their relationships and lose their self-identify," said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. "Results of the MINDSET survey of migraine-treating physicians highlight the significant need for more effective acute treatments for this debilitating neurological disease, and the desire of physicians for new treatments that demonstrate improvement over the current standard of care. The survey results therefore support the design of the ongoing MOMENTUM Phase 3 trial of AXS-07, which is being conducted in patients with a history of inadequate response to prior acute treatments, and which incorporates the very potent active comparator rizatriptan."

**Key Topline Findings from the MINDSET Survey**

*Participants and Time of Conduct*

- The survey respondents consisted of a total of 106 physicians, of whom 76% are neurologists and 24% are primary care physicians. Collectively, the survey respondents personally see and treat 51,504 migraine patients at least once per year.
- The survey was fielded in October 2019.

*Treatment Needs in Migraine*

- Improved efficacy is the most significant unmet need in the acute treatment of migraine, according to 85% of physicians, far outpacing other areas (e.g. tolerability, safety, mode of administration). The majority of their patients who switch acute migraine treatments (62%) do so because of suboptimal efficacy.
- A significant number of migraine patients experience suboptimal response to current treatments or experience difficult-to-treat migraines (39% and 31%, respectively), according to treating physicians.
- Increased risk of progression from episodic to chronic migraine associated with suboptimal acute treatment is a key concern for treating physicians, with 76% reporting that they are significantly or moderately concerned.
- Early treatment of migraine (at the earliest sign of pain) is believed to be very important by 90% of treating physicians.

*Willingness to Prescribe AXS-07*

- If AXS-07 demonstrates superior efficacy over placebo in patients with a history of inadequate response to prior acute treatments, as assessed in the ongoing MOMENTUM trial, physicians indicate they would prescribe AXS-07 to 37% of their patients with difficult-to-treat migraines.
- If AXS-07 demonstrates superior efficacy over rizatriptan, as assessed in the ongoing MOMENTUM trial, 91% of physicians report that they are more likely to prescribe AXS-07 over currently available treatments, with 56% reporting that they are significantly or moderately more likely to prescribe AXS-07.
- If AXS-07 demonstrates superior efficacy over rizatriptan as assessed in the ongoing MOMENTUM trial, 87% of physicians report that they are more likely to prescribe AXS-07 over other drugs in development, including oral CGRPs, that have not demonstrated superior efficacy to current treatments, with 56% reporting that they are significantly or moderately more likely to prescribe AXS-07.

**About the MOMENTUM Trial in Patients with History of Inadequate Response**

MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) is a Phase 3, randomized, double-blind, multicenter, controlled trial to assess the efficacy and safety of AXS-07 in the acute treatment of moderate and severe migraine in patients with a history of inadequate response to prior acute treatments. Approximately 875 eligible patients will be randomized in a 2:2:2:1 ratio to treatment with AXS-07, rizatriptan, MoSEIC™ meloxicam, or placebo. The two co-primary endpoints of the trial are the proportion of patients who are free from headache pain two hours after dosing, and the proportion of patients who no longer suffer from their most bothersome migraine-associated symptom (nausea, photophobia, or phonophobia) two hours after dosing, for AXS-07 as compared to placebo. Superiority of AXS-07 to the rizatriptan and meloxicam arms (component contribution) will be established based on sustained freedom from headache pain from two to 24 hours after dosing. The MOMENTUM study is being conducted pursuant to an FDA Special Protocol Assessment (SPA).

**About the INTERCEPT Trial Evaluating Early Treatment**

INTERCEPT (Initiating Early Control of Migraine Pain and Associated Symptoms) is a Phase 3, randomized, double-blind, multicenter, placebo-controlled trial evaluating the early treatment of migraine with AXS-07. Approximately 300 patients will be randomized in a 1:1 ratio to treatment with AXS-07 or placebo. Patients are to administer AXS-07 at the earliest sign of migraine pain. The two co-primary endpoints of the trial are the proportion of patients who are free from headache pain two hours after dosing, and the proportion of patients who no longer suffer from their most bothersome migraine-associated symptom (nausea, photophobia, or phonophobia) two hours after dosing.

**About Migraine**

Over 37 million Americans suffer from migraine according to the Centers for Disease Control, and it is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. Migraine is characterized by recurrent attacks of pulsating, often severe and disabling head pain associated with nausea, and sensitivity to light and or sound. It is estimated that migraine accounts for $78 billion in direct (e.g. doctor visits, medications) and indirect (e.g. missed work, lost productivity) costs each year in the United States [1]. Published surveys of migraine sufferers indicate that more than 70% are not fully satisfied with their current treatment, that nearly 80% would try a new therapy, and that they desire treatments that work faster, more consistently, and result in less symptom recurrence [2,3].

**About AXS-07**

AXS-07 is a novel, oral, investigational medicine with distinct dual mechanisms of action under development for the acute treatment of migraine. AXS-07 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 results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug and rizatriptan is a 5-$HT_{1B/D}$ agonist. AXS-07 is designed to provide rapid, enhanced and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is not approved by the FDA.

**About Axsome Therapeutics, Inc.**

Axsome Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. Axsome's core CNS product candidate portfolio includes four clinical-stage candidates, AXS-05, AXS-07, AXS-09, and AXS-12. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), a Phase 3 trial in major depressive disorder (MDD), and a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD). AXS-05 is also being developed for smoking cessation treatment. AXS-07 is currently in two Phase 3 trials for the acute treatment of migraine. AXS-12 is currently in a Phase 2 trial in narcolepsy. AXS-05, AXS-07, AXS-09, and AXS-12 are investigational drug products not approved by the FDA. For more information, please visit the Company's website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

**References**


1. Gooch CL, Pracht E, Borenstein AR. The burden of neurological disease in the United States: A summary report and call to action. Ann Neurol. 2017 Apr; 81(4):479-484.
2. Smelt AF, Louter MA, Kies DA, Blom JW, Terwindt GM, van der Heijden GJ, De Gucht V, Ferrari MD, Assendelft WJ. What do patients consider to be the most important outcomes for effectiveness studies on migraine treatment? Results of a Delphi study. PLoS One. 2014 Jun 16;9(6):e98933.
3. Lipton RB, Stewart WF. Acute migraine therapy: do doctors understand what patients with migraine want from therapy? Headache. 1999;39(suppl 2):S20-S26.

**Forward Looking Statements**

Certain matters discussed in this press release are “forward-looking statements”. We 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 success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, 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 our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA’s agreement with the Company’s plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee’s recommendations); the potential for the ASCEND clinical trial to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; 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 product candidates, if approved; the Company’s anticipated capital requirements, including the Company’s anticipated cash runway and the Company’s current expectations regarding its plans for future equity financings prior to the readout from its Phase 3 trials; 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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