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 04, 2024

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 2.02 Results of Operations and Financial Conditions.

On January 4, 2024, Axsome Therapeutics, Inc. (the "Company") issued a press release entitled "Axsome Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones."

For purposes of this Item 2.02, the Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1. In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As reported above, on January 4, 2024, the Company issued a press release entitled "Axsome Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones." For purposes of this Item 8.01, the full text of the press release is also being 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 4, 2024.
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 4, 2024

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

Axsome Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones

Preliminary total 4Q and full year 2023 net product revenue of $71 million and $204 million, respectively

Auvelity preliminary 4Q and full year 2023 net product sales of $49 million and $130 million, respectively

Sunosi preliminary 4Q and full year 2023 net product revenue of $22 million and $74 million, respectively

2024 anticipated regulatory milestones include NDA submission for AXS-14 in fibromyalgia and NDA resubmission for AXS-07 in migraine

2024 anticipated clinical trial readouts include topline results of the SYMPHONY trial in narcolepsy, ADVANCE-2 trial in Alzheimer's disease agitation, and the FOCUS Phase 3 trial in ADHD

2024 anticipated trial initiations include Phase 3 trials of solriamfetol in major depressive disorder, binge eating disorder, and shift work disorder

NEW YORK, Jan. 4, 2024 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing and delivering novel therapies for the management of central nervous system (CNS) disorders, today announced preliminary net product revenue for the fourth quarter and full year ended December 31, 2023.

"Axsome completed its first full year as a commercial company in 2023 and, during that time, our medicines reached approximately 100,000 unique patients. Prescriptions for Auvelity and Sunosi totaled more than 236,000 and 139,000, respectively for the full year," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Looking ahead, 2024 promises to be a busy year for us with an increased field force effort that will support continued strong commercial execution with Auvelity and Sunosi. We also anticipate multiple important clinical and regulatory milestones from our industry leading neuroscience portfolio in 2024. These include topline results from Phase 3 trials in narcolepsy, Alzheimer's disease agitation, and ADHD, NDA resubmission and submission for migraine and fibromyalgia, respectively, and initiation of Phase 3 trials in major depressive disorder, binge eating disorder, and excessive sleepiness associated with shift work disorder. Collectively, Axsome has the potential to address conditions that impact the lives of more than 150 million patients in the U.S. We are committed to developing and delivering innovative treatments with novel mechanisms of action to address unmet medical needs in serious conditions that affect brain health."

Preliminary Fourth Quarter and Full Year 2023 Net Product Revenue (Unaudited)

Based on preliminary unaudited financial information, Axsome expects total product revenue to be approximately $71 million and $204 million for the fourth quarter and full year of 2023, respectively.

- Auvelity® net product sales are expected to be approximately $49 million and $130 million for the fourth quarter and full year of 2023, respectively.
- Sunosi® net product revenue is expected to be $22 million and $74 million for the fourth quarter and full year of 2023, respectively. Net product revenue excludes $66 million in license revenue recognized by Axsome in the first quarter of 2023.

The foregoing information reflects the Company's estimate with respect to net product revenue for Auvelity and Sunosi based on currently available unaudited information. This announcement is not a comprehensive statement of Axsome's financial results and is subject to completion of Axsome's financial closing procedures. Axsome's final financial results will be issued upon completion of its closing procedures and may vary from these preliminary estimates.

2024 Development Pipeline Anticipated Milestones

Axsome is advancing an industry-leading neuroscience portfolio encompassing five innovative late-stage product candidates for 10 serious conditions, which affect more than 150 million people in the U.S. alone. 2024 anticipated milestones for key pipeline programs are summarized below.

- **Regulatory Milestones:**
  - AXS-07 for migraine, NDA resubmission (1H 2024)
  - AXS-14 for fibromyalgia, NDA submission (1Q 2024)
- **Clinical Trial Topline Results:**
  - Phase 3 SYMPHONY trial of AXS-12 in narcolepsy (1Q 2024)
  - Phase 3 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (1H 2024)
  - Phase 3 FOCUS trial of solriamfetol in attention deficit hyperactivity disorder (ADHD) in adults (2H 2024)
- **Clinical Trial Initiations:**
  - Phase 3 trial of solriamfetol in major depressive disorder (MDD) (1Q 2024)
  - Phase 3 trial of solriamfetol for binge eating disorder (BED) (1Q 2024)
  - Phase 3 trial of solriamfetol in shift work disorder (SWD) (1Q 2024)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation (2024)

About AUVELITY®

AUVELITY is a novel, oral, NMDA receptor antagonist with multimodal activity approved for the treatment of MDD in adults. AUVELITY is a proprietary extended-release oral tablet containing dextromethorphan HBr (45 mg) and bupropion HCl (105 mg). The dextromethorphan component of AUVELITY is an antagonist of the NMDA receptor (an ionotropic glutamate receptor) and a sigma-1 receptor agonist. These actions are thought to modulate glutamatergic neurotransmission. The bupropion component of AUVELITY is an aminoketone and CYP2D6 inhibitor which serves to increase and prolong the blood levels of dextromethorphan. The exact mechanism of action of Auvelity in the treatment of depression is unclear. AUVELITY received Breakthrough Therapy designation from the FDA for the treatment of MDD.

INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS AUVELITY (aw-VEHL-ah-tee)? It is a prescription oral medicine used to treat adults with major depressive disorder (MDD). It is not known if Auvelity is safe and effective for use in children.
Auvelity is not approved for uses other than the treatment of MDD. The ingredients in Auvelity, bupropion and dextromethorphan, are the same ingredients found in some other medicines approved for other uses.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AUVELITY?
Auvelity and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults, especially within the first few months of treatment or when the dose is changed. Auvelity is not for use in children.
You should pay close attention to any new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when starting or changing the dose of an antidepressant medicine.

Call your healthcare provider (HCP) or get emergency help right away if you or your loved one have any of the following symptoms, especially if they are new, worse, or worry you:

- suicidal thoughts or actions
- new or worsening depression or anxiety
- agitation or restlessness
- trouble sleeping (insomnia)
- acting aggressive, being angry violent
- an extreme increase in activity and talking (mania)
- panic attacks
- new or worsening irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

Do not take Auvelity if you:

- have or had a seizure disorder.
- have or had an eating disorder like anorexia or bulimia.
- have recently and suddenly stopped drinking alcohol or use medicines called benzodiazepines, barbiturates, or anti-seizure medicines, and you have recently suddenly stopped taking them.
- are taking a monoamine oxidase inhibitor (MAOI), have stopped taking an MAOI in the last 14 days, or are being treated with the antibiotic linezolid or intravenous methylene blue. Ask your HCP or pharmacist if you are unsure whether you take an MAOI. Do not start taking an MAOI until you have stopped taking Auvelity for at least 14 days.
- are allergic to dextromethorphan, bupropion, or any other ingredients in Auvelity.

Auvelity may cause serious side effects. Ask your HCP how to recognize the serious side effects below and what to do if you think you have one:

Seizures. There is a risk of seizures during treatment with Auvelity. The risk is higher if you take higher doses of Auvelity, have certain medical problems, or take Auvelity with certain other medicines. Do not take Auvelity with other medicines unless your healthcare provider tells you to.
If you have a seizure during treatment with Auvelity, stop taking Auvelity and call your HCP right away. Do not take Auvelity again if you have a seizure.
Increases in blood pressure (hypertension). Some people may get high blood pressure during treatment with Auvelity. Your HCP should check your blood pressure before you start taking and during treatment with Auvelity.

Manic episodes. Manic episodes may happen in people with bipolar disorder who take Auvelity. Symptoms may include:

- greatly increased energy
- racing thoughts
- unusually grand ideas
- talking more or faster than usual
- severe trouble sleeping
- reckless behavior
- excessive happiness or irritability

Unusual thoughts or behaviors. One of the ingredients in Auvelity (bupropion) can cause unusual thoughts or behaviors, including delusions (believing you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your HCP.

Eye problems (angle-closure glaucoma). Auvelity may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your HCP if you have eye pain, changes in your vision, or swelling or redness in or around the eye.

Dizziness. Auvelity may cause dizziness which may increase your risk for falls.

Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when you take Auvelity with certain other medicines. Call your HCP or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms:

- agitation
- hallucinations
- confusion
- coma
- fast heartbeat
- blood pressure changes
- dizziness
- sweating
- flushing
- high body temperature (hyperthermia)
- shaking (tremors), stiff muscles, or muscle twitching
- loss of coordination
- seizures
- nausea, vomiting, diarrhea

COMMON SIDE EFFECTS

The most common side effects of Auvelity include dizziness, headache, diarrhea, feeling sleepy, dry mouth, sexual function problems, and excessive sweating.
These are not all the possible side effects of Auvelity. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

BEFORE USING

- Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- It is important to tell your HCP if you are taking:
    - other medicines containing bupropion or dextromethorphan
    - medicines to treat depression, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants
    - theophylline
    - corticosteroids
    - oral diabetes medicines or use insulin to control your blood sugar
    - medicines to control appetite (anorectic)
    - nicotine medicines to help you stop smoking
    - street (illicit) drugs
    - benzodiazepines, sedative-hypnotic (sleep medicines), or opiates
- If you are unsure if you take any of these medicines, ask your HCP. They can tell you if it is safe to take Auvelity with your other medicines.
- Tell your HCP if you are pregnant or plan to become pregnant. Auvelity may harm your unborn baby if you take it during pregnancy. Auvelity is not recommended during pregnancy. Your HCP will prescribe another treatment for females who plan to become pregnant.
- One of the ingredients in Auvelity passes into your breast milk. Do not breastfeed during treatment with Auvelity and for 5 days after the final dose.

Tell your HCP about all your medical conditions, including if you:

- have problems with your liver or kidneys.
- have diabetes, heart disease, or high blood pressure.
- have a history of seizure, stroke, eating disorder, head injury, or have a tumor in your brain or spinal cord.
- have a history of alcohol or drug abuse.
- have a history of seizure, eating disorder, or abuse alcohol or drugs.
- have low blood sugar, low blood sodium levels, or a history of falls.
- you take certain other medicines that could interact with Auvelity.
- have or had a condition known as bipolar disorder, a family history of bipolar disorder, suicide, or depression.
- have high pressure in the eye (glaucoma).

Review the list below with your HCP. Auvelity may not be right for you if:

- you drink a lot of alcohol.
- you abuse prescription or street drugs.
- you are pregnant or plan to become pregnant.
- you are breastfeeding or plan to breastfeed.

HOW TO TAKE

- Auvelity is available by prescription only.
- Take Auvelity exactly as instructed by your HCP.
- Take Auvelity 1 time a day for 3 days, then increase your dose to 2 times a day (taken at least 8 hours apart). Do not take more than 2 Auvelity tablets in 24 hours.
- If you miss a dose, do not take an extra dose. Wait and take your next dose at the regular time. Do not take more than 1 dose of Auvelity at a time.
- Do not change your dose or stop taking Auvelity without talking to your HCP.

- Swallow Auvelity tablets whole. Do not crush, chew, or divide the tablets.
- Do not give Auvelity to other people.
- If you take too much Auvelity call your HCP or seek medical advice promptly.

LEARN MORE

For more information about Auvelity, call 866-496-2976 or visit Auvelity.com.
This summary provides basic information about Auvelity but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other HCP about Auvelity and how to take it. Your HCP is the best person to help you decide if Auvelity is right for you.

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Please see full Prescribing Information, including Boxed Warning for suicidal thoughts and behaviors, and Medication Guide.

About Sunosi® (solriamfetol)

Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi does not treat the underlying cause of OSA and Sunosi does not take the place of any device prescribed for OSA, such as a continuous positive airway pressure (CPAP) machine. It is important that you continue to use these treatments as prescribed by your healthcare provider. Sunosi received U.S. Food and Drug Administration approval on March 20, 2019 to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA and was designated a Schedule IV medicine by the U.S. Drug Enforcement Agency on June 17, 2019. SK Biopharmaceuticals Co., Ltd., the discoverer of the compound, maintains rights in 12 Asian markets, including Korea, China and Japan. Sunosi has orphan drug designation for narcolepsy in the United States. Sunosi is protected by a robust patent estate with expiries out to 2042.

More information about Sunosi, including Full Prescribing Information and Medication Guide, is available here.

Important Safety Information

Before taking SUNOSI, tell your doctor about all of your medical conditions, including if you:

- have heart problems, high blood pressure, kidney problems, diabetes, or high cholesterol.
- have had a heart attack or a stroke.
- have a history of mental health problems (including psychosis and bipolar disorders), or of drug or alcohol abuse or addiction.
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

Do not take SUNOSI if you are taking, or have stopped taking within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

What are the possible side effects of SUNOSI?

SUNOSI may cause serious side effects, including:

- **Increased blood pressure and heart rate**. SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure, and death. Your doctor should check your blood pressure before, and during, treatment with SUNOSI. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability, and agitation.** Tell your doctor if you develop any of these symptoms. Your doctor may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- decreased appetite
- problems sleeping
- nausea
- anxiety

These are not all the possible side effects of SUNOSI. Call your doctor for advice about side effects.

SUNOSI (solriamfetol) is available in 75 mg and 150 mg tablets and is a federally controlled substance (CIV) because it contains solriamfetol that can be a target for people who abuse prescription medicines or street drugs. Keep SUNOSI in a safe place to protect it from theft. Never give or sell your SUNOSI to anyone else because it may cause death or harm them and it is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see here for full Prescribing Information.

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About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing and delivering novel therapies for central nervous system (CNS) conditions that have limited treatment options. Through development of therapeutic options with novel mechanisms of action, we are transforming the approach to treating CNS conditions. At Axsome, we are committed to developing products that meaningfully improve the lives of patients and provide new therapeutic options for physicians. For more information, please visit the Company's website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

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 continued commercial success of our Sunosi® and Auvelity® products and the success of our efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; 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 revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our 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 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 statements regarding the timing of any NDA submission; whether issues identified by FDA in the complete response letter may impact the potential approvability of the Company’s NDA for AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment for the MOMENTUM clinical trial; 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 continued commercialization of Sunosi and Auvelity 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; differences between the Company’s 2023 preliminary financial information disclosed herein as compared to the Company’s final 2023 audited financial statements; delays with respect to the Company’s 2024 anticipated milestones; unforeseen circumstances or other disruptions to normal business operations arising from or related to 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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