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

August 9, 2021
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.)

22 Cortlandt Street, 16th Floor **New York, New York** (Address of principal executive offices)	**10007** (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 2.02 Results of Operations and Financial Condition.

On August 9, 2021, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 2021 and provided an update on the Company's operations. 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.

On August 9, 2021, the Company issued a press release announcing that AXS-05 has achieved primary and key secondary endpoints in the MERIT Phase 2 trial in treatment resistant depression. The full text of the press release is filed as Exhibit 99.2 hereto, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 9, 2021.
99.2	Press Release dated August 9, 2021.
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.

Dated: August 9, 2021

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

Exhibit 99.1

Axsome Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Update

Company to host conference call today at 8:00 AM Eastern

NEW YORK, August 9, 2021 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today reported financial results for the second quarter ended June 30, 2021.

“As part of the ongoing review of our NDA for AXS-05, the FDA recently notified us that they have identified deficiencies that preclude labeling discussions at this time. We are attempting to learn the nature of these deficiencies with the goal of addressing them, however, this development may lead to a delay in the potential approval of AXS-05. We will keep you informed as we learn more,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “Our other programs continue to advance. We successfully filed our NDA for AXS-07 for the acute treatment of migraine in the second quarter, and we remain on track to initiate the planned Phase 3 trial of AXS-12 for the treatment of narcolepsy this quarter. The buildout of our team and infrastructure is also continuing as we work towards our goal of delivering potentially life-changing medicines to people living with serious CNS conditions.”

Business Update

For the many people facing unsatisfactory treatments for CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. The Company is developing a portfolio of differentiated, patent-protected, CNS product candidates with four in active clinical development.

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome’s novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for the following indications: major depressive disorder (MDD), Alzheimer’s disease (AD) agitation, and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designations for MDD and for AD agitation.

- **Depression:** Axsome’s New Drug Application (NDA) for AXS-05 for the treatment of MDD was granted Priority Review and is currently under review by the FDA. On July 30, 2021, the Company received a letter from the FDA stating that it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The letter stated further that the notification does not reflect a final decision on the information under review. The letter did not state what the deficiencies are. In response to the Company’s inquiries regarding the nature of the deficiencies since receipt of the letter, the FDA has informed the Company that their review is ongoing, but have not yet communicated any details regarding the nature of the deficiencies. The Prescription Drug User Fee Act (PDUFA) target action date for the NDA is August 22, 2021.

  Axsome has completed the MERIT trial, a Phase 2, randomized, double-blind, placebo-controlled, relapse prevention trial of AXS-05 in treatment resistant depression (TRD) patients. In a separate release issued this morning, Axsome announced that AXS-05 met the primary and key secondary endpoint in the trial. AXS-05 substantially and significantly delayed the time to relapse of depression (p=0.002, primary endpoint), and prevented relapse of depression (p=0.004, key secondary endpoint), compared to placebo.

- **AD Agitation:** Axsome is conducting the ACCORD study, a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial to evaluate the efficacy and safety of AXS-05 in the treatment of Alzheimer’s disease (AD) agitation. Axsome anticipates completion of the trial in the fourth quarter of 2022.

- **Smoking Cessation:** Axsome is scheduled to meet with the FDA in the third quarter to discuss the continued clinical development of AXS-05 as an aid to smoking cessation treatment. Axsome previously announced positive results from a Phase 2 trial of AXS-05 for smoking cessation treatment conducted under a research collaboration between Axsome and Duke University.

AXS-07

AXS-07 (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for the acute treatment of migraine.

- **Migraine:** Axsome submitted an NDA for AXS-07 for the acute treatment of migraine in the second quarter. The Company intends to announce the FDA's decision regarding its acceptance of the NDA filing in the third quarter.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for the treatment of narcolepsy.

- **Narcolepsy:** Axsome is on track to initiate a Phase 3 trial of AXS-12 in the treatment of narcolepsy in the third quarter. The planned Phase 3 trial will be a randomized, double-blind, placebo-controlled, parallel-group study.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the management of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine.

- **Fibromyalgia:** In June 2021, Axsome announced it had completed a pre-NDA meeting with the FDA for AXS-14. Axsome anticipates submitting an NDA for AXS-14 for the management of fibromyalgia in the fourth quarter of 2022, pending successful completion of manufacturing and other activities related to the product candidate. AXS-14 has previously met the primary endpoints and demonstrated positive and statistically significant results in a Phase 3 and in a Phase 2 trial for the management of fibromyalgia.

Commercial and Launch-Readiness Activities

Axsome continues with preparations for a potential commercial launch of AXS-05 for the treatment of MDD, if approved, and for a subsequent launch of AXS-07 for the acute treatment of migraine, if approved, including technology implementation and team build:

- Axsome's Digital Centric Commercialization™ (DCC) platform design and implementation is now complete and testing of the platform for execution at launch is underway.
- Axsome's field leadership team is now fully staffed and field force representative hiring has commenced. The Company anticipates having all field representatives on-board by launch.
- The market access team continues to engage in permitted ongoing discussion with payers, ensuring awareness of Axsome and of AXS-05's product profile, and is actively setting up comprehensive patient support services.

2021 Anticipated Milestones

- **Regulatory and Commercial:**
    - AXS-05 for MDD, PDUFA target action date (August 22, 2021)
    - AXS-07 for migraine, NDA acceptance decision (3Q 2021)

- AXS-05 for smoking cessation, FDA meeting (3Q 2021)
- AXS-05 for MDD, commercial launch, if approved (4Q 2021)

- **Clinical Trial Initiations:**
  - Phase 3 trial of AXS-12 in the treatment of narcolepsy (3Q 2021)

Upcoming Scientific Conferences

Axsome is scheduled to present data at the following upcoming scientific conferences:

- International Headache Congress (IHC), September 8-12, 2021

Second Quarter 2021 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $14.5 million for the three months ended June 30, 2021 and $10.5 million for the comparable period in 2020. The increase was driven by costs to support the NDA filings and personnel expense which includes an increase in headcount along with an increase in stock compensation expense.
- **General and administrative (G&A) expenses:** G&A expenses were $16.3 million for the three months ended June 30, 2021 and $7.2 million for the comparable period in 2020. The increase was primarily due to pre-commercial activities and personnel expense which includes an increase in headcount along with an increase in stock compensation expense.
- **Net loss:** Net loss was $32.3 million, or $(0.86) per share, for the three months ended June 30, 2021 compared to a net loss of $18.3 million, or $(0.49) per share, for the comparable period in 2020.
- **Cash:** At June 30, 2021, Axsome had $141.2 million of cash compared to $183.9 million at December 31, 2020.
- **Shares outstanding:** At June 30, 2021, Axsome had 37,648,948 shares of common stock outstanding.

Financial Guidance

- Axsome believes that its cash at June 30, 2021, along with the remaining committed capital from the $225 million term loan facility, is sufficient to fund anticipated operations, based on the current operating plan, which includes costs for the potential commercial launch of AXS-05 in MDD and AXS-07 in migraine, into at least 2024.
- Axsome expects that its operating expenses will increase year over year as we continue to build out the commercial function and further advance our pipeline.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss second quarter 2021 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (844) 698-4029 (toll-free domestic) or (647) 253-8660 (international), and use the conference ID 2545435. The 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 Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing 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 intensely committed to developing products that meaningfully improve the lives of patients and provide additional 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 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, whether potential filing issues or issues identified by FDA during the substantive review may impact the potential approvability of the Company's NDA submission for AXS-05 in MDD or the timing of such approval, and whether the FDA will agree with the Company's discontinuation of the bupropion treatment arm of the ADVANCE study in accordance with the independent data monitoring committee's recommendations); the successful submission of and approval by the FDA of an 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 potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, 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 amount of capital required for the Company's commercial launch of its product candidates, and the potential impact on the Company's anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; 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.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

Statements of Operations Information:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 14,503,326	$ 10,542,957	$ 31,099,014	$ 38,064,357
General and administrative	$ 16,344,361	$ 7,235,877	$ 27,592,734	$ 12,205,934
Total operating expenses	30,847,687	17,778,834	58,691,748	50,270,291
Loss from operations	(30,847,687)	(17,778,834)	(58,691,748)	(50,270,291)
Interest and amortization of debt discount (expense) income	(1,436,522)	(548,158)	(2,852,431)	(540,847)
Net loss	$ (32,284,209)	$ (18,326,992)	$ (61,544,179)	$ (50,811,138)
Net loss per common share, basic and diluted	$ (0.86)	$ (0.49)	$ (1.64)	$ (1.37)
Weighted average common shares outstanding, basic and diluted	37,595,069	37,100,770	37,512,716	37,081,064

Balance Sheet Information:

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 141,219,090	$ 183,876,453
Total assets	143,264,750	186,134,323
Loan payable, current and long-term	48,882,599	48,321,848
Accumulated deficit	(340,340,272)	(278,796,093)
Stockholders' equity	$ 71,436,620	$ 113,792,909

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Exhibit 99.2

Axsome Therapeutics Announces AXS-05 Achieves Primary and Key Secondary Endpoints in the MERIT Phase 2 Trial in Treatment Resistant Depression

AXS-05 significantly delayed the time to relapse of depression compared to placebo (p=0.002, primary endpoint)

AXS-05 significantly prevented relapse of depression over at least 6 months compared to placebo (p=0.004, key secondary endpoint)

NEW YORK, August 9, 2021 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that AXS-05, a novel, oral, investigational NMDA receptor antagonist with multimodal activity, met the primary and key secondary endpoints in the MERIT (Mechanistic Evaluation of Response in TRD) Phase 2 trial, and substantially and statistically significantly prevented relapse of depressive symptoms compared to placebo in patients with treatment resistant depression (TRD). The MERIT study was a randomized, double-blind, placebo-controlled, relapse prevention, multi-center, U.S. trial, which evaluated 44 TRD patients. Patients in stable remission after treatment with AXS-05 were randomized to continue treatment with AXS-05 or to discontinue AXS-05 and switch to placebo.

AXS-05 met the primary endpoint by substantially and statistically significantly delaying the time to relapse of depressive symptoms as compared to placebo (p=0.002), with no relapses observed with AXS-05 over at least 6 months of double-blind treatment. AXS-05 also met the key secondary endpoint of relapse prevention, based on the rates of relapse during the double-blind treatment period (0.0% of AXS-05 patients, 36.4% of patients switched from AXS-05 to placebo, p=0.004).

AXS-05 was well tolerated in the trial. There were no treatment-emergent adverse events reported in >1 patient in the AXS-05 group. One subject in the AXS-05 group experienced two serious adverse events (gout and bacteremia), both of which were deemed not related to the study medication.

A new drug application (NDA) for AXS-05 for the treatment of major depressive disorder is under Priority Review by the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) target action date of August 22, 2021.

About the MERIT Study

MERIT was a Phase 2, randomized, double-blind, placebo-controlled, multi-center study to evaluate AXS-05 compared to placebo in preventing relapse of depressive symptoms in patients with treatment resistant depression (TRD). Treatment resistance was defined as ongoing symptoms of depression despite receiving treatment with two or more prior antidepressants during the current major depressive episode. TRD patients were enrolled into MERIT from the long-term, open-label Phase 3 trial of AXS-05, and were required to be in stable remission prior to randomization. Stable remission was defined as at least two consecutive Montgomery-Åsberg Depression Rating Scale (MADRS) scores of ≤12, separated by at least 4 weeks.

A total of 44 TRD patients who experienced a stable remission after up to 12 months of open-label treatment with AXS-05 (45 mg dextromethorphan-105 mg bupropion) tablets twice daily, were randomized 1:1 to continue AXS-05, or to discontinue AXS-05 and switch to placebo, in a double-blind fashion, for at least 26 weeks or until a relapse of depressive symptoms occurred. Relapse was defined in the study by one or more of the following: MADRS total score ≥18 for 2 consecutive assessments; a ≥2-point increase from randomization in the Clinical Global Impression of Severity, with a minimum CGI-S score of 4, for 2 consecutive assessments; hospitalization due to worsening of depression or risk of suicide; investigator determination of relapse or need for additional antidepressant or treatment switch.

The primary endpoint in the study was time from randomization to relapse calculated by the Kaplan-Meier estimates and the hazard ratio. The key secondary endpoint, to assess relapse prevention, was the percentage of patients without relapse.

About Major Depressive Disorder

Major depressive disorder (MDD) is a debilitating, chronic, biologically-based disorder characterized by low mood, inability to feel pleasure, feelings of guilt and worthlessness, low energy, and other emotional and physical symptoms, and which impairs social, occupational, educational, or other important functioning. In severe cases, MDD can result in suicide. According to the National Institutes of Health, an estimated 7% of U.S. adults, or approximately 19 million, experience MDD each year[1]. According to the World Health Organization (WHO), depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease[2]. Nearly two-thirds of diagnosed and treated patients do not experience adequate treatment response with currently available first-line therapy[3], highlighting the need for additional therapies with new mechanisms of action. The majority of initial failures also fail second-line treatment. Patients diagnosed with MDD are defined as having treatment resistant depression (TRD) if they have failed to respond to two or more antidepressant therapies.

About AXS-05

AXS-05 (dextromethorphan-bupropion) is a novel, oral, patent-protected, investigational NMDA receptor antagonist with multimodal activity under development for the treatment of major depressive disorder and other central nervous system (CNS) disorders. AXS-05 utilizes a proprietary formulation and dose of dextromethorphan and bupropion, and Axsome's metabolic inhibition technology, to modulate the delivery of the components. The dextromethorphan component of AXS-05 is an uncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist, also known as a glutamate receptor modulator, which is a novel mechanism of action, meaning it works differently than currently approved oral therapies for major depressive disorder. The dextromethorphan component of AXS-05 is also a sigma-1 receptor agonist. The bupropion component of AXS-05 serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor. AXS-05 is currently covered by more than 100 issued U.S. and international patents, with expiration dates out to 2040. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designations for the treatment of MDD and for treatment of Alzheimer's disease agitation. A new drug application (NDA) for AXS-05 for the treatment of major depressive disorder is under Priority Review by the FDA, with a Prescription Drug User Fee Act (PDUFA) target action date of August 22, 2021. AXS-05 is not approved by the FDA.

About Axsome Therapeutics, Inc.

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References

1. Substance Abuse and Mental Health Services Administration. (2020). Results from the 2019 National Survey on Drug Use and Health. Retrieved from https://www.samhsa.gov/data/.

2. World Health Organization. Fact Sheets: Depression.

3. Rush AJ, et al. (2007) Am J. Psychiatry 163:11, pp. 1905-1917 (STAR*D Study).

Forward Looking Statements

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