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): April 29, 2022

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	**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 Condition.

On May 2, 2022, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2022 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 April 29, 2022, the Company received a Complete Response Letter (the "CRL") from the U.S. Food and Drug Administration (the "FDA") regarding its New Drug Application (the "NDA") for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07. The principal reasons given in the CRL relate to chemistry, manufacturing, and controls (CMC) considerations. The Company believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA. The Company issued a press release announcing the CRL on May 2, 2022, which is attached hereto as Exhibit 99.2.

In March 2022, the Company previously announced that the Company entered into a definitive agreement to acquire Sunosi® (solriamfetol) from Jazz Pharmaceuticals. The waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 expired as of April 29, 2022. As previously disclosed, the transaction is structured to be completed in sequential closings for the U.S. and ex-U.S. territories. The Company expects the U.S. transaction to close in the second quarter of 2022, and the ex-U.S. transaction to close within 60 days following the U.S. transaction close.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Q1 2022 Press Release dated May 2, 2022.
99.2	CRL Press Release dated May 2, 2022.
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: May 2, 2022

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

Axsome Therapeutics Reports First Quarter 2022 Financial Results and Provides Business Update

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

NEW YORK, May 2, 2022 /PRNewswire/ – 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 first quarter ended March 31, 2022.

“Axsome is poised to transform into a commercial entity potentially as early as this month, a direct result of our dedicated team’s focused execution. Between pending FDA action on our NDA for AXS-05 in depression and the expected closing of our acquisition of Sunosi, Axsome is well-positioned to potentially make two important new medicines available to patients living with serious CNS disorders in the coming months,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “With regards to AXS-07 for migraine, we look forward to engaging with the FDA to address the issues in the recent complete response letter, with the goal of an expeditious resubmission of that NDA. The rest of our rich pipeline continues to progress with an NDA filing for AXS-14 in fibromyalgia, and topline results from our Phase 3 trials of AXS-12 in narcolepsy and AXS-05 in Alzheimer’s disease agitation anticipated in 2023.”

Business Update

Axsome is committed to developing medicines that meaningfully improve the lives of patients living with CNS disorders. The Company is advancing 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. The Company has received and agreed to Postmarketing Requirements/Commitments proposed by the FDA. Based on this interaction, the Company anticipates potential FDA action on the NDA in the second quarter of 2022.
- **Alzheimer’s Disease 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. The Company is evaluating the design of the study and will provide an update following consultation with the FDA.
- **Smoking Cessation:** Axsome plans to proceed to a pivotal Phase 2/3 trial in this indication. The Company intends to provide information on the timing of initiation of this study in 2022.

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 received a Complete Response Letter (CRL) from the FDA regarding its NDA for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA and the FDA did not request any new clinical trials to support the approval of AXS-07. The principal reasons given in the CRL relate to chemistry, manufacturing, and controls (CMC) considerations. The Company believes that the issues raised in the CRL are addressable, and intends to provide potential timing for a resubmission following consultation with the FDA.

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 conducting the SYMPHONY study, a Phase 3 randomized, multicenter, double-blind, placebo-controlled, parallel-group trial of AXS-12 in the treatment of narcolepsy. Enrollment in the trial is progressing and topline results are anticipated in the first half of 2023.

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:** Manufacturing and other activities related to the planned submission of an NDA for AXS-14 for the management of fibromyalgia are ongoing. The Company expects to submit the NDA in 2023. 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.

Corporate

- In March 2022, Axsome announced that the Company entered into a definitive agreement to acquire Sunosi® (solriamfetol) from Jazz Pharmaceuticals (NASDAQ: JAZZ). Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA). Sunosi net sales were $57.9 million in 2021, representing year-over-year growth of 104%.

  The waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 has expired. The transaction is structured to be completed in sequential closings for the U.S. and ex-U.S. territories. The Company expects the U.S. transaction to close in the second quarter of 2022, and the ex-U.S. transaction to close within 60 days following the U.S. transaction close.

Commercial and Launch-Readiness Activities

Axsome is prepared for a commercial launch of AXS-05 for the treatment of MDD, if approved, and is ready to assume commercialization of Sunosi upon closing of that acquisition:

- The AXS-05 field force team build is complete with all signed offers contingent upon approval. The Company anticipates having all field representatives for the product candidate on-board by launch.
- Activities are underway to ensure a timely and seamless transition of Sunosi into the Axsome infrastructure upon closing of the transaction.
- Axsome's first-in-class Digital Centric Commercialization™ (DCC) platform will be used to augment commercialization of both AXS-05 and Sunosi.

Anticipated Milestones

- **Corporate**
  - Sunosi acquisition U.S. and ex-U.S. transaction closings (2Q, 3Q 2022, respectively)
- **Regulatory and Commercial:**
  - AXS-05 for MDD, FDA action on NDA
  - AXS-05 for MDD, commercial launch, if approved
  - AXS-07 for migraine, NDA resubmission
  - AXS-14 for fibromyalgia, NDA submission (2023)
- **Clinical Trial Readouts:**
  - Phase 3 SYMPHONY trial of AXS-12 in narcolepsy, topline data (1H 2023)
  - Phase 3 ACCORD trial of AXS-05 for Alzheimer's disease agitation, topline data (1H 2023)

First Quarter 2022 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $12.6 million for the three months ended March 31, 2022 and $16.6 million for the comparable period in 2021. The decrease was driven by expenses related to the NDA filing which occurred in the prior comparable period.
- **General and administrative (G&A) expenses:** G&A expenses were $25.7 million for the three months ended March 31, 2022 and $11.2 million for the comparable period in 2021. The increase was primarily related to pre-commercial activities and personnel expense, along with an increase in non-cash stock compensation expense.
- **Net loss:** Net loss was $39.6 million, or $(1.03) per share, for the three months ended March 31, 2022 compared to a net loss of $29.3 million, or $(0.78) per share, for the comparable period in 2021. The net loss for the current period included $7.6 million of non-cash stock compensation expense compared to $3.7 million in the comparable period.
- **Cash:** At March 31, 2022, Axsome had $84.7 million of cash compared to $86.5 million at December 31, 2021.
- **Shares outstanding:** At March 31, 2022, Axsome had 38,883,445 shares of common stock outstanding.

Financial Guidance

- Axsome believes that its current cash, along with the remaining committed capital from the $300 million term loan facility, is sufficient to fund anticipated operations into 2024, based on the current operating plan, which includes the potential launch of AXS-05 in MDD, and the acquisition and commercialization of Sunosi.
- Axsome expects that its operating expenses will increase year over year as it continues to build out the commercial function and further advance its pipeline.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss first quarter 2022 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (844) 200-6205 (toll-free domestic) or (929) 526-1599 (international) and use the conference ID 152950. 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 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 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; 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 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 12,585,141	$ 16,595,689
General and administrative	25,703,731	11,248,372
Total operating expenses	38,288,872	27,844,061
Loss from operations	(38,288,872)	(27,844,061)
Interest and amortization of debt discount (expense)	(1,343,439)	(1,415,909)
Net loss	$ (39,632,311)	$ (29,259,970)
Net loss per common share, basic and diluted	$ (1.03)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	38,323,167	37,429,450

Balance Sheet Information:

	March 31, 2022	**December 31, 2021**
Cash and cash equivalents	$ 84,707,782	$ 86,472,854
Total assets	88,560,261	87,785,058
Total current liabilities	24,549,582	23,065,184
Loan payable, current and long-term	49,312,665	49,089,522
Accumulated deficit	(448,831,396)	(409,199,085)
Stockholders' equity	$ 14,698,014	$ 15,630,352

Axsome Contact:
Mark Jacobson
Chief Operating Officer
Axsome Therapeutics, Inc.
22 Cortlandt Street, 16th Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Axsome Therapeutics Receives FDA Complete Response Letter for New Drug Application for AXS-07 for the Acute Treatment of Migraine

No clinical efficacy or safety issues raised and no additional clinical studies required by FDA to support approval

Company plans to engage with FDA toward expeditious resolution of outstanding items

NEW YORK, May 2, 2022 /PRNewswire/ – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that the Company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07.

The principal reasons given in the CRL relate to chemistry, manufacturing, and controls (CMC) considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA.

“It is our goal to work with the FDA to fully understand and adequately address their comments, so that we can make this important new medicine available to patients with migraine as quickly as possible,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “The approval of AXS-07 would offer a much-needed new multi-mechanistic treatment option for the millions of people living with this debilitating neurological condition.”

The NDA is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials, which demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls.

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, rapidly absorbed, multi-mechanistic investigational medicine for the acute treatment of migraine, consisting 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-$HT_{1B/1D}$ agonist. AXS-07 is designed to provide rapid, enhances and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is covered by more than 80 issued U.S. and international patents which provide protection out to 2036. AXS-07 is not approved by the FDA.

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 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.

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, 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; 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 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 Contact:
Mark Jacobson
Chief Operating Officer
Axsome Therapeutics, Inc.
22 Cortlandt Street, 16th Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com