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): May 06, 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 Condition.

On May 6, 2024, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2024 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 6, 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: May 6, 2024

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

Exhibit 99.1

Axsome Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

Total 1Q 2024 net product revenue of $75.0 million, representing 160% year-over-year growth

Auvelity® 1Q 2024 net product sales of $53.4 million, representing 240% year-over-year growth

Sunosi® 1Q 2024 net product revenue of $21.6 million representing 64% year-over-year growth

Contract executed with second large group purchasing organization (GPO) for potential coverage of Auvelity

Positive pivotal Phase 3 trial results of AXS-12 in narcolepsy announced

Topline results of ADVANCE-2 Phase 3 trial of AXS-05 in Alzheimer's disease agitation and FOCUS Phase 3 trial of solriamfetol in ADHD both anticipated 2H 2024

ACCORD-2 Phase 3 randomized withdrawal trial of AXS-05 in Alzheimer's disease agitation initiated; enrollment completion anticipated mid-year 2024

PARADIGM and ENGAGE Phase 3 trials of solriamfetol in major depressive disorder and binge eating disorder, respectively, initiated

NDA resubmission for AXS-07 in migraine and NDA submission for AXS-14 in fibromyalgia both targeted for 2Q 2024

NEW YORK, May 6, 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 financial results for the first quarter of 2024.

"The first quarter was marked by strong financial performance for our on-market products which are delivering important and differentiated treatment options for patients living with depression, narcolepsy and obstructive sleep apnea," said Herriot Tabuteau, MD, CEO of Axsome Therapeutics. "We also significantly advanced our innovative neuroscience pipeline in the quarter. We announced positive Phase 3 results for AXS-12 in narcolepsy, a major step toward making this new medicine available to patients living with this debilitating condition, and we launched two pivotal trials of solriamfetol in major depressive disorder and binge eating disorder. In the coming months we look forward to resubmitting our NDA for AXS-07 in migraine, and to submitting our NDA for AXS-14 in fibromyalgia. Our Phase 3 ADVANCE-2 trial of AXS-05 in Alzheimer's disease agitation remains on track for completion in the second half of 2024. Further, we added to the robustness of this clinical development program with the initiation of the ACCORD-2 study of AXS-05 in Alzheimer's disease agitation, a Phase 3 randomized withdrawal trial, for which we expect to complete enrollment mid-year 2024."

First Quarter 2024 Financial Highlights

- Total net product revenue for the first quarter of 2024 was $75.0 million, representing 160% year-over-year growth. Total net product revenue for the comparable period in 2023 was $28.8 million. Overall total revenue for the first quarter of 2023 was $94.6 million which included a one-time $65.7 million upfront payment received for the out-licensing of Sunosi commercialization rights in Europe and certain countries in the Middle East and North Africa region.
- Auvelity net product sales were $53.4 million for the first quarter of 2024, representing 240% year-over-year growth. Auvelity net product sales for the comparable period in 2023 were $15.7 million.

- Sunosi net product revenue was $21.6 million for the first quarter of 2024, consisting of $20.7 million in net product sales and $0.9 million in royalty revenue associated with sales in out-licensed territories, representing 64% year-over-year growth. Sunosi net product revenue for the comparable period in 2023 was $13.2 million, consisting of $12.9 million in net product sales and $0.3 million in royalty revenue.
- Total cost of revenue was $6.3 million for the first quarter of 2024. Total cost of revenue for the comparable period in 2023 was $7.6 million. The 2023 comparable period includes $5.0 million in out-license fee sharing expense.
- Research and development (R&D) expenses were $36.8 million for the first quarter of 2024, compared to $17.8 million for the comparable period in 2023, respectively. The increase was primarily related to the initiation and continuation of solriamfetol Phase 3 trials in major depressive disorder, binge eating disorder, and ADHD, ongoing trials of AXS-05 and AXS-12, manufacturing associated with the anticipated NDAs for AXS-07 and AXS-14, post-marketing commitments for Auvelity and Sunosi, and higher personnel costs including non-cash stock-based compensation.
- Selling, general, and administrative (SG&A) expenses were $99.0 million for the first quarter of 2024, compared to $74.2 million for the comparable period in 2023. The increase was primarily related to commercialization activities for Auvelity and Sunosi specifically around field force expansion and organizational growth, including non-cash stock-based compensation.
- Net loss for the first quarter of 2024 was $68.4 million or $(1.44) per share, compared to a net loss of $11.2 million, or $(0.26) per share for the comparable period in 2023. The net loss in the first quarter of 2024 reflects $21.0 million in non-cash charges. The 2023 comparable period includes $62.0 million in net gain from the Sunosi out-licensing.
- Cash and cash equivalents totaled $331.4 million at March 31, 2024, compared to $386.2 million at December 31, 2023.
- Shares of common stock outstanding were 47,464,575 at March 31, 2024.

Financial Guidance

- Axsome believes that its current cash is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan.

Commercial Highlights

Auvelity

- Approximately 95,000 prescriptions were written for Auvelity in the first quarter of 2024, representing a 12% sequential increase versus the fourth quarter of 2023.
- Payer coverage for Auvelity across all channels is stable at approximately 70% of all covered lives. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 48% and approximately 100%, respectively.
- Effective May 1, 2024, Axsome has contracted with a second large group purchasing organization (GPO) for potential formulary coverage of Auvelity. Pharmacy benefit managers and health plans under this GPO are now able to make coverage decisions for Auvelity based on the contracted terms. Axsome has now contracted with two of the three largest GPOs for Auvelity.

Sunosi

- Approximately 42,000 prescriptions were written for Sunosi in the U.S. in the first quarter of 2024, representing an 1.6% decrease versus the fourth quarter of 2023.

- Sunosi maintains broad payer coverage in the commercial channel with 95% of lives covered. Currently 83% of total lives across all channels are covered.

Development Pipeline

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

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational NMDA receptor antagonist and sigma-1 agonist being developed for Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for AD agitation.

- **Alzheimer's Disease Agitation:** Axsome is conducting the ADVANCE-2 study, a Phase 3, placebo-controlled, parallel group trial to evaluate the efficacy and safety of AXS-05 for the treatment of AD agitation. Patients completing ADVANCE-2 may enter a long-term open label safety extension trial. The Company anticipates completion of ADVANCE-2 in the second half of 2024.

  Axsome recently initiated the ACCORD-2 study, a Phase 3, double-blind, placebo-controlled, randomized withdrawal trial to evaluate the efficacy and safety of AXS-05 in the treatment of AD agitation. In this study, patients from the Company's long-term open label safety extension trial are treated with AXS-05 and monitored for treatment response based on the Cohen-Mansfield Agitation Inventory (CMAI). Approximately 140 patients who experience a treatment response are planned to be randomized into the double-blind treatment period, in a 1:1 ratio, to continue treatment with AXS-05 or to switch to placebo, for up to 26 weeks or until a relapse of agitation occurs. The primary endpoint will be the time from randomization to relapse. The Company anticipates completion of enrollment in this study around mid-year.

  ACCORD-2 adds a fourth controlled efficacy trial to the robust development program for AXS-05 in AD agitation, which now includes two parallel group trials (ADVANCE-1 and ADVANCE-2) and two randomized withdrawal trials (ACCORD-1 and ACCORD-2).

- **Smoking Cessation:** Axsome plans to initiate a pivotal Phase 2/3 trial in this indication in 2024.

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:** Activities for the resubmission of the Company's New Drug Application (NDA) for AXS-07 for the acute treatment of migraine are nearing completion. The Company is on track to resubmit the NDA in the second quarter of 2024. No additional clinical efficacy or safety trials have been requested by the FDA for a resubmission of the NDA. The Company expects the NDA resubmission to be designated as Class 2 which would be subject to a six-month review.

  Axsome is conducting the EMERGE study, a multicenter, Phase 3, single-group trial evaluating the efficacy and safety of AXS-07 in the acute treatment of migraine headache in adults with a prior inadequate response to an oral CGRP inhibitor. The Company anticipates topline results from the EMERGE study in the second half of 2024.

AXS-12

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

- **Narcolepsy:** In March 2024, Axsome announced positive topline results from the SYMPHONY trial, a Phase 3, randomized, double-blind, multicenter, placebo-controlled trial of AXS-12 in patients with narcolepsy. AXS-12 achieved the primary endpoint by significantly reducing the frequency of cataplexy attacks as compared to placebo in patients with narcolepsy. AXS-12 also reduced excessive daytime sleepiness severity (EDS), improved cognitive function, reduced overall narcolepsy severity, and improved patient function and quality of life, as compared to placebo. AXS-12 was well tolerated in the trial.

  A Phase 3 open label safety extension trial of AXS-12 is currently ongoing with completion anticipated in the fourth quarter of 2024.

  In March 2024, the Company also announced topline results from the CRESCENDO (Characterizing Patient Perspectives on Unmet Needs in Narcolepsy) survey of 203 narcolepsy patients with cataplexy (narcolepsy type 1 or NT1) who are currently receiving treatment. The results demonstrated high rates of persistent symptoms with 77%, 64%, and 74% continuing to experience cataplexy, EDS, and cognitive impairment, respectively, despite being on current treatments. CRESCENDO was conducted by a third-party research firm that worked with Narcolepsy Network to ensure patient privacy. Narcolepsy Network is a national non-profit patient support organization for people with narcolepsy, idiopathic hypersomnia and related sleep disorders.

AXS-14

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

- **Fibromyalgia:** Pre-submission activities for the Company's NDA for AXS-14 for the management of fibromyalgia are nearing completion. The Company is targeting submission of the NDA in the second quarter of 2024. 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.

Solriamfetol

Solriamfetol is Axsome's dopamine and norepinephrine reuptake inhibitor and TAAR1 agonist in development for the treatment of attention deficit hyperactivity disorder (ADHD), major depressive disorder (MDD), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

- **Attention Deficit Hyperactivity Disorder:** Axsome is conducting the FOCUS study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial to assess the efficacy and safety of solriamfetol for the treatment of ADHD in adults. The Company anticipates topline results from the FOCUS study in the second half of 2024.
- **Major Depressive Disorder:** In March 2024, Axsome initiated the PARADIGM study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial of solriamfetol for the treatment of MDD. The Company anticipates topline results from the PARADIGM study in 2025.
- **Binge Eating Disorder:** In March 2024, Axsome initiated the ENGAGE study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial of solriamfetol for the treatment of BED. The Company anticipates topline results from the ENGAGE study in 2025.
- **Shift Work Disorder:** The Company is on track initiate a Phase 3 trial of solriamfetol for the treatment of excessive sleepiness (ES) associated with SWD in the second quarter of 2024.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-07 for migraine, NDA resubmission (2Q 2024)
  - AXS-14 for fibromyalgia, NDA submission (2Q 2024)
- **Clinical Trial Topline Results:**
  - Phase 3 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (2H 2024)
  - Phase 3 open-label safety extension trial of AXS-12 in narcolepsy (2H 2024)
  - Phase 3 FOCUS trial of solriamfetol in ADHD in adults (2H 2024)
  - Phase 3 PARADIGM trial of solriamfetol in major depressive disorder (2025)
  - Phase 3 ENGAGE trial of solriamfetol in binge eating disorder (2025)
  - Phase 3 EMERGE trial of AXS-07 in migraine with inadequate response to oral CGRP inhibitors (2H 2024)
- **Clinical Trial Initiations and Progress:**
  - Phase 3 trial of solriamfetol in shift work disorder, initiation (2Q 2024)
  - Phase 3 ACCORD-2 trial of AXS-05 for Alzheimer's disease agitation, enrollment completion (mid-year 2024)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation, initiation (2024)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss first quarter 2024 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic). 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 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; 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.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

Axsome Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 331,441	$ 386,193
Accounts receivables, net	101,434	94,820
Inventories, net	15,583	15,135
Prepaid and other current assets	12,032	8,115
Total current assets	460,490	504,263
Equipment, net	812	846
Right-of-use asset - operating lease	6,411	6,772
Goodwill	12,042	12,042
Intangible asset, net	51,697	53,286
Non-current inventory and other assets	14,276	11,027
Total assets	$ 545,728	$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 53,791	$ 40,679
Accrued expenses and other current liabilities	82,716	90,501
Operating lease liability, current portion	1,153	1,267
Contingent consideration, current	6,388	6,407
Total current liabilities	144,048	138,854
Contingent consideration, non-current	70,000	73,300
Loan payable, long-term	178,689	178,070
Operating lease liability, long-term	7,258	7,035
Finance lease liability, long-term	1,697	—
Total liabilities	401,692	397,259
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 47,464,575 and 47,351,363 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,047,959	1,026,543
Accumulated deficit	(903,928)	(835,571)
Total stockholders' equity	144,036	190,977
Total liabilities and stockholders' equity	$ 545,728	$ 588,236

Axsome Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
(In thousands, except share and per share amounts)

	Three months ended March 31,	
	2024	2023
Revenues:		
Product sales, net	$ 74,096	$ 28,569
License revenue	—	65,735
Royalty revenue	903	272
Total revenues	74,999	94,576
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	6,297	7,556
Research and development	36,830	17,793
Selling, general and administrative	98,970	74,191
Gain in fair value of contingent consideration	(1,412)	(162)
Intangible asset amortization	1,589	1,572
Total operating expenses	142,274	100,950
Loss from operations	(67,275)	(6,374)
Interest expense, net	(1,082)	(2,264)
Loss before income taxes	(68,357)	(8,638)
Income tax expense	—	(2,580)
Net loss	$ (68,357)	$ (11,218)
Net loss per common share, basic and diluted	$ (1.44)	$ (0.26)
Weighted average common shares outstanding, basic and diluted	47,393,563	43,523,631

Axsome Contacts:

Investors:
Mark Jacobson
Chief Operating Officer
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Media:
Darren Opland
Director, Corporate Communications
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 929-837-1065
Email: dopland@axsome.com
www.axsome.com