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): August 05, 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 August 5, 2024, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 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 August 5, 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: August 5, 2024

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 2024 Financial Results and Provides Business Update

Total 2Q 2024 net product revenue of $87.2 million, representing 87% year-over-year growth

Auvelity® 2Q 2024 net product sales of $65.0 million, representing 135% year-over-year growth

Sunosi® 2Q 2024 net product revenue of $22.1 million representing 16% year-over-year growth

NDA for AXS-07 in migraine resubmitted

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

Topline results of ACCORD-2 Phase 3 randomized withdrawal trial of AXS-05 in Alzheimer's disease agitation anticipated 2H 2024; target enrollment reached

Topline results of FOCUS Phase 3 trial of solriamfetol in ADHD anticipated 2H 2024

SUSTAIN Phase 3 trial of solriamfetol in shift work disorder initiated

NDA submission for AXS-14 in fibromyalgia expected 3Q 2024

NEW YORK, August 5, 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 second quarter of 2024.

"We delivered another robust quarter driven by focused commercial execution and continued pipeline advancement," said Herriot Tabuteau, MD, CEO of Axsome Therapeutics. "We continue to see strong demand for Auvelity and increased commercial payer coverage by more than 22 million lives as of August 1st. The NDA for AXS-07 in migraine has been resubmitted, and we are tracking to submit the NDA for AXS-14 in fibromyalgia in the third quarter. Trials in four new indications for solriamfetol are now underway, and we remain on track to deliver topline results from the FOCUS Phase 3 trial in ADHD in the second half of this year. For our AXS-05 program in Alzheimer's disease agitation, the ADVANCE-2 Phase 3 trial continues to progress, and the ACCORD-2 Phase 3 trial has reached target enrollment, positioning us to potentially report topline results for both of these pivotal trials in the second half of the year."

Second Quarter 2024 Financial Highlights

- Total net product revenue for the second quarter of 2024 was $87.2 million, representing 87% year-over-year growth. Total net product revenue for the comparable period in 2023 was $46.7 million.
- Auvelity net product sales were $65.0 million for the second quarter of 2024, representing 135% year-over-year growth. Auvelity net product sales for the comparable period in 2023 were $27.6 million.
- Sunosi net product revenue was $22.1 million for the second quarter of 2024, consisting of $21.5 million in net product sales and $0.6 million in royalty revenue associated with sales in out-licensed territories, representing 16% year-over-year growth. Sunosi net product revenue for the comparable period in 2023 was $19.1 million, consisting of $18.4 million in net product sales and $0.7 million in royalty revenue.
- Total cost of revenue was $8.1 million for the second quarter of 2024. Total cost of revenue for the comparable period in 2023 was $4.6 million.

- Research and development (R&D) expenses were $49.9 million for the second quarter of 2024, compared to $20.6 million for the comparable period in 2023. The increase was primarily related to the initiation and continuation of solriamfetol Phase 3 trials in major depressive disorder, ADHD, and binge eating disorder, ongoing trials of AXS-05 and AXS-12, manufacturing costs associated with AXS-07 and AXS-14, post-marketing commitments for Auvelity and Sunosi, and higher personnel costs, including non-cash stock-based compensation, due to organizational growth.

- Selling, general, and administrative (SG&A) expenses were $103.6 million for the second quarter of 2024, compared to $78.9 million for the comparable period in 2023. The increase was primarily related to commercialization expenses largely driven by field force expansion and higher personnel costs, including non-cash stock-based compensation, due to organizational growth.

- Net loss for the second quarter of 2024 was $79.3 million or $(1.67) per share, compared to a net loss of $67.2 million or $(1.54) per share for the comparable period in 2023. The net loss in the second quarter of 2024 reflects $26.0 million in non-cash charges.

- Cash and cash equivalents totaled $315.7 million at June 30, 2024, compared to $386.2 million at December 31, 2023.

- Shares of common stock outstanding were 47,801,578 at June 30, 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 123,000 prescriptions were written for Auvelity in the second quarter of 2024, representing a 29% sequential increase versus the first quarter of 2024.

- Payer coverage for Auvelity in the commercial channel increased from 48% of lives covered last quarter to 60% of lives covered as of August 1. The proportion of lives covered in the government channel (Medicare and Medicaid) remains at approximately 100%. Payer coverage for Auvelity across all channels is now at approximately 76% of all covered lives. Axsome expects coverage to continue to expand and evolve.

Sunosi

- Approximately 45,000 prescriptions were written for Sunosi in the U.S. in the second quarter of 2024, representing an 8% increase versus the first quarter of 2024.

- 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 pipeline encompassing five innovative, late-stage, patent-protected product candidates for 9 serious psychiatric and neurologic conditions, which affect more than 140 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 the treatment of 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 evaluating the efficacy and safety of AXS-05 in AD agitation. Patients completing ADVANCE-2 may enter a long-term open label safety extension trial. The Company anticipates topline results from the ADVANCE-2 trial in the second half of 2024.

  Axsome is also conducting the ACCORD-2 study, a Phase 3, double-blind, placebo-controlled, randomized withdrawal trial evaluating the efficacy and safety of AXS-05 in AD agitation. The enrollment target for the ACCORD-2 trial has been met and the Company now anticipates topline results in the second half of 2024.

- **Smoking Cessation:** Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in 2024.

AXS-07

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

- **Migraine:** The Company has resubmitted its New Drug Application (NDA) for AXS-07 for the acute treatment of migraine. 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 for 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 trial 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 being developed for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for narcolepsy.

- **Narcolepsy:** Axsome is conducting a Phase 3 open label safety extension trial of AXS-12 with topline results anticipated in the fourth quarter of 2024. AXS-12 has previously met the primary endpoints and demonstrated positive and statistically significant results in the completed SYMPHONY Phase 3 and CONCERT Phase 2 trials in patients with narcolepsy.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, highly selective investigational norepinephrine reuptake inhibitor being developed 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 substantially complete. The Company expects to submit the NDA in the third 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 being developed 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 evaluating the efficacy and safety of solriamfetol for the treatment of ADHD in adults. The Company anticipates topline results in the second half of 2024.

- **Major Depressive Disorder:** Axsome is conducting the PARADIGM study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol for the treatment of MDD. The Company anticipates topline results in 2025.

- **Binge Eating Disorder:** Axsome is conducting the ENGAGE study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol for the treatment of BED. The Company anticipates topline results in 2025.

- **Shift Work Disorder:** Axsome has initiated the SUSTAIN (Studying Solriamfetol Modulation of TAAR-1, Dopamine, and Norepinephrine in Shift Work Disorder) study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol for the treatment of SWD in adults. The Company anticipates topline results in 2026.

Business Update

- In June 2024, Axsome announced that it has resolved patent litigation with Unichem Laboratories Ltd. (Unichem) seeking approval to market a generic equivalent of Sunosi in the United States. The Company entered into a settlement agreement with Unichem Laboratories Ltd., which permits Unichem to begin selling its generic version of Sunosi on June 30, 2042, or earlier under certain circumstances. The June 30, 2042 date is also subject to potential extension for pediatric exclusivity.

Anticipated Milestones

- **Regulatory:**
    - AXS-14 for fibromyalgia, NDA submission (3Q 2024)
- **Clinical Trial Topline Results:**
    - Phase 3 ADVANCE-2 trial of AXS-05 in Alzheimer's disease agitation (2H 2024)
    - Phase 3 ACCORD-2 trial of AXS-05 in 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 EMERGE trial of AXS-07 in patients with migraine with inadequate response to oral CGRP inhibitors (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 SUSTAIN trial of solriamfetol in shift work disorder (2026)
- **Clinical Trial Initiations and Progress:**
    - Pivotal Phase 2/3 trial of AXS-05 in smoking cessation, initiation (2024)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss second quarter 2024 financial results and provide a business update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic). The live webcast can be accessed on the Investors page 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”. The Company 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 the Company’s Sunosi® and Auvelity® products and the success of the Company’s efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company’s ability to maintain and expand payer coverage; the success, timing and cost of the Company’s ongoing clinical trials and anticipated clinical trials for the Company’s current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company’s ability to fully fund the Company’s disclosed clinical trials, which assumes no material changes to the Company’s currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company’s 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 the Company’s current product candidates; the Company’s ability to fund additional clinical trials to continue the advancement of the Company’s product candidates; the timing of and the Company’s ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, the Company’s 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 the Company’s 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; the Company’s ability to convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, 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)

	June 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 315,657	$ 386,193
Accounts receivables, net	120,342	94,820
Inventories, net	15,220	15,135
Prepaid and other current assets	11,808	8,115
Total current assets	463,027	504,263
Equipment, net	724	846
Right-of-use asset - operating lease	6,071	6,772
Goodwill	12,042	12,042
Intangible asset, net	50,107	53,286
Non-current inventory and other assets	16,255	11,027
Total assets	$ 548,226	$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 61,340	$ 40,679
Accrued expenses and other current liabilities	116,771	90,501
Operating lease liability, current portion	1,419	1,267
Contingent consideration, current	7,040	6,407
Total current liabilities	186,570	138,854
Contingent consideration, non-current	69,620	73,300
Loan payable, long-term	179,330	178,070
Operating lease liability, long-term	6,829	7,035
Finance lease liability, long-term	3,025	—
Total liabilities	445,374	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, 47,801,578 and 47,351,363 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,086,120	1,026,543
Accumulated deficit	(983,273)	(835,571)
Total stockholders' equity	102,852	190,977
Total liabilities and stockholders' equity	$ 548,226	$ 588,236

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 86,520	$ 46,017	$ 160,616	$ 74,586
License revenue	—	—	—	65,735
Royalty revenue	646	683	1,549	955
Total revenues	87,166	46,700	162,165	141,276
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	8,055	4,599	14,352	12,155
Research and development	49,853	20,581	86,683	38,374
Selling, general and administrative	103,554	78,935	202,524	153,126
Loss in fair value of contingent consideration	2,160	6,053	748	5,891
Intangible asset amortization	1,590	1,589	3,179	3,161
Total operating expenses	165,212	111,757	307,486	212,707
Loss from operations	(78,046)	(65,057)	(145,321)	(71,431)
Interest expense, net	(1,299)	(2,730)	(2,381)	(4,994)
Loss before income taxes	(79,345)	(67,787)	(147,702)	(76,425)
Income tax benefit (expense)	—	617	—	(1,963)
Net loss	$ (79,345)	$ (67,170)	$ (147,702)	$ (78,388)
Net loss per common share, basic and diluted	$ (1.67)	$ (1.54)	$ (3.11)	$ (1.80)
Weighted average common shares outstanding, basic and diluted	47,573,229	43,669,820	47,482,602	43,597,131

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