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

November 12, 2024

Total 3Q 2024 net product revenue of $104.8 million, representing 81% year-over-year growth

Auvelity® 3Q 2024 net product sales of $80.4 million, representing 113% year-over-year growth

Sunosi® 3Q 2024 net product revenue of $24.4 million representing 21% year-over-year growth

Second expansion of Auvelity psychiatry sales force planned for 1Q 2025

NDA resubmission for AXS-07 for the treatment of migraine accepted by the FDA with PDUFA goal date of January 31, 2025

Topline results of ADVANCE-2 and ACCORD-2 Phase 3 trials of AXS-05 in Alzheimer's disease agitation on track for 4Q 2024

Topline results of ENCORE Phase 3 trial of AXS-12 in narcolepsy on track for 4Q 2024

Topline results of FOCUS Phase 3 trial of solriamfetol in ADHD anticipated 1Q 2025

Topline results of PARADIGM Phase 3 trial of solriamfetol in MDD anticipated 1Q 2025

NDA submission for AXS-14 for the management of fibromyalgia anticipated November 2024

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

NEW YORK, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced financial results for the third quarter of 2024 and provided a general business update.

"In the third quarter, we continued our strong commercial performance and advanced our innovative, industry-leading, late-stage development pipeline towards important near-term milestones," said Herriot Tabuteau, MD, Chief Executive Officer. "In response to continued strong demand growth, a second expansion of the Auvelity sales force is planned for the first quarter of 2025. In addition, with the January 31, 2025, PDUFA date for our AXS-07 product candidate for migraine fast approaching, commercial preparations are underway for a timely and successful launch, if approved."

"We expect a busy end to the year with several clinical catalysts anticipated, including a planned simultaneous release of topline results from the ongoing Phase 3 ADVANCE-2 and ACCORD-2 trials of AXS-05 in Alzheimer's disease agitation in the fourth quarter," Dr. Tabuteau added. "Our growth as an organization positions us well to potentially deliver multiple innovative new medicines to the millions of individuals living with central nervous system disorders in the U.S. Importantly, we have the resources in hand to execute our operating plans and create substantial value for shareholders."

Third Quarter 2024 Financial Highlights

- Total net product revenue for the third quarter of 2024 was $104.8 million, representing 81% year-over-year growth. Total net product revenue for the comparable period in 2023 was $57.8 million.
- Auvelity net product sales were $80.4 million for the third quarter of 2024, representing 113% year-over-year growth. Auvelity net product sales for the comparable period in 2023 were $37.7 million.
- Sunosi net product revenue was $24.4 million for the third quarter of 2024, representing 21% year-over-year growth, which consisted of $23.4 million in net product sales and $1.0 million in royalty revenue associated with sales in out-licensed territories. Sunosi net product revenue for the comparable period in 2023 was $20.1 million, consisting of $19.4 million in net product sales and $0.7 million in royalty revenue.
- Total cost of revenue was $8.4 million for the third quarter of 2024. Total cost of revenue for the comparable period in 2023 was $6.5 million.
- Research and development (R&D) expenses were $45.4 million for the third quarter of 2024, compared to $28.8 million for the comparable period in 2023. The increase was primarily related to the Company's ongoing Phase 3 trials of solriamfetol

in four new indications and of AXS-05 in Alzheimer's disease agitation, chemistry, manufacturing, and controls costs associated with pipeline products, and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Selling, general, and administrative (SG&A) expenses were $95.6 million for the third quarter of 2024, compared to $83.2 million for the comparable period in 2023. The increase was primarily related to commercialization expenses for Auvelity and Sunosi and higher personnel costs, including non-cash stock-based compensation, associated with organizational growth.

- Net loss for the third quarter of 2024 was $64.6 million or $(1.34) per share, compared to a net loss of $62.2 million or $(1.32) per share for the comparable period in 2023. The net loss in the third quarter of 2024 reflects $40.9 million in non-cash charges, including a fair market value adjustment for contingent consideration of $16.4 million.

- Cash and cash equivalents totaled $327.3 million at September 30, 2024, compared to $386.2 million at December 31, 2023.

- Shares of common stock outstanding were 48,436,108 at September 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 144,000 prescriptions were written for Auvelity in the third quarter of 2024, representing an increase of 108% compared to the same period in 2023, and an increase of 17% compared to the second quarter of 2024.

- Payer coverage for Auvelity across all channels is at approximately 78% of all covered lives. The proportion of lives covered for Auvelity in the commercial and government (Medicare and Medicaid) channels are approximately 63% and 100%, respectively.

- In response to demand growth and in anticipation of continued expansion and evolution of covered lives, Axsome is planning a second expansion of its Auvelity psychiatry sales force to approximately 300 sales representatives. The expansion is expected to complete in the first quarter of 2025.

Sunosi

- Approximately 47,000 prescriptions were written for Sunosi in the U.S. in the third quarter of 2024, representing an increase of 15% compared to the same period in 2023, and an increase of 5% compared to the second quarter of 2024.

- Payer coverage for Sunosi across all channels is at approximately 83% of all covered lives. The proportion of lives covered for Sunosi in the commercial and government channels are approximately 95% and 60%, respectively.

Development Pipeline

Axsome is advancing an industry-leading neuroscience pipeline encompassing five innovative, late-stage, patent-protected product candidates for nine serious psychiatric and neurological conditions. 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, sigma-1 agonist, and aminoketone CYP2D6 inhibitor being developed for the treatment of Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 has been granted FDA Breakthrough Therapy designation for AD agitation.

- **Alzheimer's Disease Agitation:** The comprehensive development program of AXS-05 in AD agitation consists of four pivotal, Phase 3, placebo-controlled efficacy trials, including the completed, positive ADVANCE-1 and ACCORD-1 trials, and the ongoing ADVANCE-2 and ACCORD-2 trials.

  ADVANCE-2 is a randomized, double-blind, placebo-controlled, parallel group trial. ACCORD-2 is a double-blind, placebo-controlled, randomized withdrawal trial. Target enrollment in both trials has been reached. The Company remains on track to report topline results from the ADVANCE-2 and ACCORD-2 trials in the fourth quarter and anticipates doing so simultaneously.

Smoking Cessation: Axsome plans to initiate a pivotal Phase 2/3 trial of AXS-05 in smoking cessation in 2025.

AXS-07

AXS-07 (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational selective COX-2 inhibitor and 5-$HT_{1B/1D}$ agonist being developed for the acute treatment of migraine.

- **Migraine:** Axsome's New Drug Application (NDA) for AXS-07 for the acute treatment of migraine is currently under review by the FDA with a PDUFA goal date of January 31, 2025.

  Axsome is conducting the EMERGE study, a Phase 3, single-group, multicenter 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 remains on track to announce topline results from the EMERGE trial in the fourth quarter of 2024.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, highly selective investigational 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 the ENCORE study, a two-period Phase 3 trial evaluating the long-term efficacy and safety of AXS-12 in narcolepsy, consisting of a 24-week open-label period followed by a 3-week, double-blind, placebo-controlled, randomized withdrawal period. Enrollment in the ENCORE trial is complete, and the Company remains on track to report topline results from the trial in the fourth quarter of 2024.

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:** Axsome is completing preparations for the submission of the NDA for AXS-14 for the management of fibromyalgia and expects to submit the NDA to the FDA in November 2024.

Solriamfetol

Solriamfetol is Axsome's dopamine and norepinephrine reuptake inhibitor (DNRI), TAAR1 agonist, and 5-HT_{1A} 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 in ADHD in adults. The Company anticipates completion of enrollment in the FOCUS trial in December 2024 and topline results in the first quarter of 2025.

- **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 in MDD. The study will examine the effect of solriamfetol in MDD patients with and without excessive daytime sleepiness (EDS). The Company anticipates completion of enrollment in the PARADIGM trial in the fourth quarter of 2024 and topline results in the first quarter of 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 in BED. The Company anticipates topline results from the trial in 2025.

- **Shift Work Disorder:** Axsome is conducting the SUSTAIN study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial evaluating the efficacy and safety of solriamfetol in SWD in adults. The Company anticipates topline results from the trial in 2026.

Scientific Presentations

- In September 2024, the Company presented multiple data analyses at Sleep Europe 2024, including results from the SYMPHONY Phase 3 trial of AXS-12 in narcolepsy and findings from the CRESCENDO patient survey underscoring the unmet needs of patients with type 1 narcolepsy.

- In October and November 2024, the Company presented multiple data analyses at Psych Congress 2024 and NEI Congress 2024, respectively, including new findings from a pooled analysis of the GEMINI and ASCEND clinical trials of Auvelity supporting its differentiated safety and tolerability profile.

Corporate Update

- In August 2024, Axsome announced that the patent litigation with Sandoz Inc. (Sandoz) related to Sunosi (solriamfetol) was dismissed following Sandoz's withdrawal of its ANDA for a generic equivalent of Sunosi. As a result, the litigation with Sandoz has been dismissed without prejudice.

Anticipated Milestones

- **Regulatory:**
  - AXS-14 for fibromyalgia, NDA submission (November 2024)
  - AXS-07 for migraine, PDUFA goal date (January 31, 2025)
- **Clinical Trial Topline Results:**
  - Phase 3 ADVANCE-2 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024)
  - Phase 3 ACCORD-2 trial of AXS-05 in Alzheimer's disease agitation (4Q 2024)
  - Phase 3 ENCORE trial of AXS-12 in narcolepsy (4Q 2024)
  - Phase 3 EMERGE trial of AXS-07 in patients with migraine with inadequate response to oral CGRP inhibitors (4Q 2024)
  - Phase 3 FOCUS trial of solriamfetol in ADHD in adults (1Q 2025)
  - Phase 3 PARADIGM trial of solriamfetol in major depressive disorder (1Q 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 (2025)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss its third quarter 2024 financial results and provide a business update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic) or +1 (201) 389-0851 (international). A live webcast of the conference call can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the conference call will be available for approximately 30 days following the live event.

About Axsome Therapeutics

Axsome Therapeutics is a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) conditions. We deliver scientific breakthroughs by identifying critical gaps in care and develop differentiated products with a focus on novel mechanisms of action that enable meaningful advancements in patient outcomes. Our industry-leading neuroscience portfolio includes FDA-approved treatments for major depressive disorder and excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea and multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States. Together, we are on a mission to solve some of the brain's biggest problems so patients and their loved ones can flourish.

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)

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 327,341	$ 386,193
Accounts receivables, net	124,096	94,820
Inventories, net	14,265	15,135
Prepaid and other current assets	13,411	8,115
Total current assets	479,113	504,263
Equipment, net	683	846
Right-of-use asset - operating lease	5,730	6,772
Goodwill	12,042	12,042
Intangible asset, net	48,501	53,286
Non-current inventory and other assets	15,389	11,027
Total assets	$ 561,458	$ 588,236
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 64,253	$ 40,679
Accrued expenses and other current liabilities	122,176	90,501
Operating lease liability, current portion	1,627	1,267
Contingent consideration, current	8,131	6,407
Total current liabilities	196,187	138,854
Contingent consideration, non-current	82,980	73,300
Loan payable, long-term	180,002	178,070
Operating lease liability, long-term	6,440	7,035
Finance lease liability, long-term	2,951	—
Total liabilities	468,560	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, 48,436,108 and 47,351,363 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively)	5	5
Additional paid-in capital	1,140,768	1,026,543
Accumulated deficit	(1,047,875)	(835,571)
Total stockholders' equity	92,898	190,977
Total liabilities and stockholders' equity	$ 561,458	$ 588,236

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023

Revenues:				
Product sales, net	$ 103,736	$ 57,127	$ 264,352	$ 131,713
License revenue	—	—	—	65,735
Royalty revenue	1,026	667	2,575	1,622
Total revenues	104,762	57,794	266,927	199,070
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	8,437	6,532	22,789	18,687
Research and development	45,388	28,767	132,071	67,141
Selling, general and administrative	95,564	83,188	298,088	236,314
Loss (Gain) in fair value of contingent consideration	16,391	(180)	17,139	5,711
Intangible asset amortization	1,606	1,607	4,785	4,768
Total operating expenses	167,386	119,914	474,872	332,621
Loss from operations	(62,624)	(62,120)	(207,945)	(133,551)
Interest expense, net	(1,978)	(757)	(4,359)	(5,751)
Loss before income taxes	(64,602)	(62,877)	(212,304)	(139,302)
Income tax benefit (expense)	—	678	—	(1,285)
Net loss	$ (64,602)	$ (62,199)	$ (212,304)	$ (140,587)
Net loss per common share, basic and diluted	$ (1.34)	$ (1.32)	$ (4.45)	$ (3.14)
Weighted average common shares outstanding, basic and diluted	48,140,519	47,117,196	47,703,508	44,783,380

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