Axsome Therapeutics Provides Preliminary Fourth Quarter and Full Year 2024 Net Revenue

January 13, 2025

Auvelity preliminary 4Q and full year 2024 net product sales of $92.6 million and $291.4 million, respectively

Sunosi preliminary 4Q and full year 2024 net product revenue of $25.7 million and $93.8 million, respectively

NEW YORK, Jan. 13, 2025 (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 preliminary net product revenue for the fourth quarter and full year ended December 31, 2024.

"We delivered strong revenue growth in 2024 and significantly advanced our industry leading neuroscience pipeline, including achievement of positive Phase 3 results for AXS-05 in Alzheimer's disease agitation and for AXS-12 in narcolepsy, supporting planned regulatory filings for these indications and products in 2025," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We also look to carry our commercial momentum into 2025 with continued growth for Auvelity and Sunosi, and are making active launch preparations for AXS-07 for the acute treatment of migraine, if approved."

Preliminary Fourth Quarter and Full Year 2024 Net Product Revenue (Unaudited)

Based on preliminary unaudited financial information, Axsome expects total product revenue to be approximately $118.3 million and $385.2 million for the fourth quarter and full year of 2024, respectively.

- Auvelity® net product sales are expected to be approximately $92.6 million and $291.4 million for the fourth quarter and full year of 2024, respectively.
- Sunosi® net product revenue is expected to be approximately $25.7 million and $93.8 million for the fourth quarter and full year of 2024, respectively.

The foregoing information reflects the Company's estimate with respect to net product revenue for Auvelity and Sunosi based on currently available unaudited information. This announcement is not a comprehensive statement of Axsome's financial results and is subject to completion of Axsome's financial closing procedures. Axsome's final financial results will be issued upon completion of its closing procedures and may vary from these preliminary estimates.

About Axsome Therapeutics, Inc.

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, including statements regarding the ability of the ACCORD and ADVANCE clinical trials to support the filing of an NDA for Alzheimer's disease agitation; 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; differences between the Company's 2024 preliminary financial information disclosed herein as compared to the Company's final 2024 audited financial statements; the fact that estimated net product revenue is not a comprehensive statement of the Company's financial results and is subject to completion of Company's financial closing procedures; 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.

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