Axsome Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

February 27, 2023

Total fourth quarter net product sales of $24.4 million

Auvelity® launched October 19th, with fourth quarter net product sales of $5.2 million

Sunosi® fourth quarter net product sales of $19.2 million

Sunosi® license agreement for EU announced – $66 million upfront, potential milestones up to $101 million

Pro forma fourth quarter net cash in excess of $300 million

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

NEW YORK, Feb. 27, 2023 (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 reported financial results for the fourth quarter and full year ended December 31, 2022.

"The past year was a landmark for Axsome, which saw us bring our first fully in-house end-to-end developed drug to market, potentially transforming the treatment landscape for depression and providing the potential to improve the lives of millions of patients and their loved ones," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "With two differentiated products in Auvelity and Sunosi now commercialized, encouraging early launch metrics for Auvelity, a broad and advancing late-stage CNS pipeline, and a strong financial position, Axsome is well positioned to continue to deliver significant value to patients and shareholders. We are looking forward to another milestone filled year which has already kicked off with an important licensing agreement for Sunosi in Europe that serves to expand patient access to this important treatment while providing significant potential future value to Axsome. Over the next 12 to 18 months, we look to continuing to execute on the commercialization of Auvelity and Sunosi, initiating or reading out at least four registration trials in indications of high unmet need, and potentially filing four new NDAs."

Fourth Quarter 2022 Financial Highlights

- Total net sales were $24.4 million and $50.0 million for the fourth quarter and full year of 2022 respectively, compared to none for the 2021 comparable periods. Auvelity was launched on October 19, 2022 and had U.S. net sales of $5.2 million for the fourth quarter of 2022. No Auvelity sales were reported by Axsome for the 2021 comparable period reflecting the timing of the Auvelity approval and launch. Net sales of Sunosi to Axsome were $19.2 million and $44.8 million for the fourth quarter and full year of 2022 respectively. Axsome began selling Sunosi in the U.S. in May 2022 and in certain international markets in November 2022. Therefore no Sunosi sales were reported by Axsome for the 2021 comparable periods.
- Total cost of product sales were $2.3 million and $5.2 million for the fourth quarter and full year of 2022 respectively, compared to none for the 2021 comparable periods.
- Research and development (R&D) expenses were $14.7 million and $57.9 million for the fourth quarter and full year of 2022 respectively, compared to $13.8 million and $58.1 million for the comparable periods in 2021, respectively. The increase for the fourth quarter was primarily related to higher costs associated with ongoing clinical trials, including post-marketing commitments for Sunosi and Auvelity.
- Selling, general, and administrative (SG&A) expenses were $61.5 million and $159.3 million for the fourth quarter and full year of 2022 respectively, compared to $18.8 million and $66.6 million for the comparable periods in 2021, respectively. The increases were primarily related to commercial activities for Sunosi and Auvelity, including sales force onboarding, marketing spend, and higher non-cash stock compensation expense.
- Net loss was $61.2 million, or $(1.41) per share, for the fourth quarter of 2022, compared to a net loss of $34.0 million, or $(0.90) per share, for the comparable period in 2021. The net loss for the fourth quarter of 2022 included $10.8 million of non-cash stock compensation expense compared to $5.9 million in the comparable period in 2021. Net loss was $187.1 million, or $(4.60) per share, for the full year of 2022, compared to a net loss of $130.4 million, or $(3.47) per share, for the

full year of 2021. The net loss for the full year 2022 included $37.7 million of non-cash stock compensation expense compared to $20.8 million for the full year 2021.

- Cash and cash equivalents totaled $200.8 million at December 31, 2022, compared to $86.5 million at December 31, 2021. In January 2023, Axsome amended its loan agreement with Hercules Capital increasing the size of the facility to $350 million, reducing the interest rate, and extending the maturity and interest-only period, while accessing a new $55 million tranche. In addition, In February 2023 the Company received approximately $66 million from the out-licensing of ex-U.S. rights to Sunosi. Inclusive of these events, the pro forma December 31, 2022 cash balance is in excess of $300 million.

- Shares of common stock outstanding were 43,498,617 at December 31, 2022.

Financial Guidance

- Axsome believes that its current cash, along with the remaining committed capital from the $350 million term loan facility, is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan, which includes the continued commercialization of Sunosi and Auvelity.

- Axsome expects that its operating expenses will increase year over year as the Company commercializes Sunosi and Auvelity and continues to advance its pipeline.

Commercial Highlights

Auvelity

- Axsome commercially launched Auvelity on October 19, 2022. Early prescription trends reflect strong adoption from prescribers and patients.

- Effective January 2023, Axsome has contracted with one of the largest group purchasing organizations (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. Medicaid coverage became effective in all states except Texas on January 1, and Medicare coverage is expected to become available approximately 6 months post launch.

- Axsome's comprehensive patient and provider support services continue to perform as planned. The Auvelity on My Side program is designed to help clinicians and patients easily access Auvelity and the program includes: the Auvelity Savings Card to reduce out-of-pocket expenses for qualifying patients, telehealth services, HCP samples, and prior authorization assistance.

Sunosi

- U.S. Sunosi performance in the fourth quarter reflects continued focus on commercial execution. Fourth quarter U.S. Sunosi total prescriptions increased by 11% versus the fourth quarter of 2021, and by 1% versus the third quarter of 2022. Full year Sunosi total prescriptions grew 21% in 2022 vs. 2021.

- Sunosi has broad payer coverage in the commercial channel with 96% of lives covered. Currently 83% of total lives are covered.

- In the fourth quarter of 2022, Axsome closed the ex-U.S. acquisition of Sunosi. Subsequently in February 2023, Axsome licensed the marketing rights for Sunosi in Europe and certain countries in the Middle East and North Africa (MENA) to Pharmanovia. In consideration, Axsome received an upfront payment of $66M, with potential milestones up to $101M. Axsome will receive a royalty percentage in the mid-twenties on net sales in the licensed territory. Pharmanovia will assume responsibility for all local clinical and regulatory activities and requirements including studies in pediatric patients with narcolepsy.

Development Pipeline

Axsome is advancing a portfolio of differentiated, patent-protected, CNS product candidates with five in active clinical development. 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 with multimodal activity 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:** In November 2022, Axsome announced positive topline results from the ACCORD trial, a Phase 3, placebo-controlled, randomized withdrawal trial of AXS-05 in patients with AD agitation. The study met its primary

and key secondary endpoints by substantially and statistically significantly delaying the time to relapse and preventing relapse of agitation symptoms as compared to placebo.

The Company is conducting the ADVANCE-2 study, a Phase 3, placebo-controlled, parallel group trial to assess 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. Based on current enrollment trends, the Company now anticipates completion of ADVANCE-2 in the first half of 2024, versus prior guidance of mid-2025.

Axsome recently received feedback from the FDA on the clinical development program of AXS-05 in AD agitation. The FDA feedback indicated that an NDA for AXS-05 in this indication should include placebo-controlled safety information from the ongoing ADVANCE-2 trial, as well as long-term safety data in the target patient population consisting of at least 300 patients treated for six months and 100 patients treated for one year. Based on this guidance, the Company intends to submit an NDA for AXS-05 after completion of the ongoing ADVANCE-2 and open-label safety extension trials.

- **Smoking Cessation:** Axsome plans to proceed to a pivotal Phase 2/3 trial in this indication. The Company anticipates initiation of this study in the fourth quarter of 2023.

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:** Manufacturing activities related to the planned resubmission of the New Drug Application (NDA) for AXS-07 for the acute treatment of migraine are ongoing. The Company anticipates resubmission of the NDA in the second half of 2023. 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.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, investigational 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 continue to be anticipated in the first half of 2023.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, investigational 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.

Solriamfetol

Solriamfetol is Axsome's dual-acting dopamine and norepinephrine reuptake inhibitor in development for the treatment of attention deficit hyperactivity disorder (ADHD).

- **ADHD:** The Company is preparing to initiate a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of solriamfetol in adults with ADHD in the first half of 2023.

- **Cognitive function:** In October, the Company announced that solriamfetol met the primary endpoint in the SHARP study and significantly improved cognitive function, as measured by the DSST RBANS, in cognitively impaired patients with excessive daytime sleepiness associated with obstructive sleep apnea, compared to placebo (p=0.009). Superiority of solriamfetol as compared to placebo was further demonstrated using patient-reported measures of cognitive function.

Anticipated Milestones

- **Regulatory and Commercial:**
    - AXS-07 for migraine, NDA resubmission (2H 2023)
    - 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 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (1H 2024)
- **Clinical Trial Initiations:**
  - Phase 3 trial of solriamfetol for ADHD in adults (1H 2023)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation (4Q 2023)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss fourth quarter 2022 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 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; 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, 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

Axsome Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 200,841,955	$ 86,472,854
Accounts receivables, net	37,698,868	—
Inventories, net	4,319,921	—
Prepaid and other current assets	2,780,665	45,286
Total current assets	245,641,409	86,518,140
Equipment, net	722,515	283,846
Right-of-use asset - operating lease	420,298	660,162

Goodwill	10,310,000	—
Intangible asset, net	59,660,772	—
Non-current inventory and other assets	14,721,101	322,910
Total assets	$ 331,476,095	$ 87,785,058
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 38,605,312	$ 13,149,329
Accrued expenses and other current liabilities	51,630,813	9,295,180
Operating lease liability, current portion	424,673	620,675
Contingent consideration, current	5,900,000	—
Total current liabilities	96,560,798	23,065,184
Contingent consideration, non-current	31,100,000	—
Loan payable, long-term	94,258,888	49,089,522
Total liabilities	221,919,686	72,154,706
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at December 31, 2022 and December 31, 2021, respectively)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 43,498,617 and 37,816,794 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively)	4,350	3,782
Additional paid-in capital	705,884,795	424,825,655
Accumulated deficit	(596,332,736)	(409,199,085)
Total stockholders' equity	109,556,409	15,630,352
Total liabilities and stockholders' equity	$ 331,476,095	$ 87,785,058

Axsome Therapeutics, Inc.
Consolidated Statements of Operations

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 24,371,528	$ -	$ 50,037,106	$ -
Operating expenses:				
Cost of product sales (excluding amortization and depreciation)	2,290,928	-	5,197,595	-
Research and development	14,693,083	13,781,453	57,947,447	58,060,725
Selling, general and administrative	61,497,347	18,826,588	159,253,661	66,646,205
Loss in fair value of contingent consideration	4,200,350	-	3,298,230	-
Intangible asset amortization	1,606,789	-	4,139,228	-
Total operating expenses	84,288,497	32,608,041	229,836,161	124,706,930
Loss from operations	(59,916,969)	(32,608,041)	(179,799,055)	(124,706,930)
Interest expense, net	(1,322,643)	(1,368,095)	(7,334,596)	(5,696,062)
Net loss	$ (61,239,612)	$ (33,976,136)	$ (187,133,651)	$ (130,402,992)
Net loss per common share, basic and diluted	$ (1.41)	$ (0.90)	$ (4.60)	$ (3.47)
Weighted average common shares outstanding, basic and diluted	43,447,309	37,764,545	40,665,941	37,618,599

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