Axsome Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

February 20, 2024

Total 4Q and full year 2023 net product revenue of $71.5 million and $204.9 million, respectively, representing year-over-year growth of 193% and 309%

Auvelity 4Q and full year 2023 net product sales of $49.0 million and $130.1 million, respectively, during the first full year of launch

Sunosi 4Q and full year 2023 net product revenue of $22.5 million and $74.8 million, respectively, representing 17% and 67% year-over-year growth

NDA submission for AXS-14 in fibromyalgia and NDA resubmission for AXS-07 in migraine, both anticipated in 1H 2024

Topline results of the SYMPHONY Phase 3 trial in narcolepsy anticipated in 1Q 2024

Topline results of the ADVANCE-2 Phase 3 trial in Alzheimer's disease agitation and the FOCUS Phase 3 trial in ADHD expected in 2H 2024

Initiation of Phase 3 trials of solriamfetol in major depressive disorder, binge eating disorder, and shift work disorder expected 1Q 2024

NEW YORK, Feb. 20, 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 reported financial results for the fourth quarter and full year of 2023.

"2023 was a transformational year for Axsome, based on successful commercial execution as well as substantial pipeline advancement and expansion. During our first full year as a commercial company, Auvelity and Sunosi were prescribed for more than 100,000 patients combined. We expanded our Auvelity neuropsychiatry sales force and progressed our NDAs for AXS-07 in migraine and AXS-14 in fibromyalgia. We advanced our Phase 3 trials of AXS-12 in narcolepsy and AXS-05 in Alzheimer's disease agitation, initiated a Phase 3 pivotal trial program for solriamfetol in ADHD, and announced three additional new indications for solriamfetol," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We expect to continue the momentum in 2024 as we drive further growth for our two currently marketed products, and potentially submit two NDAs for migraine and fibromyalgia, read out three Phase 3 trials in narcolepsy, Alzheimer's disease agitation, and ADHD, and, in the near term, initiate an equal number of new pivotal trials in depression, binge eating disorder, and shift work disorder. Enrollment in the SYMPHONY Phase 3 trial of AXS-12 in narcolepsy is now complete and we are on track to report topline results this quarter."

Fourth Quarter 2023 and Full Year Financial Highlights

- Total net product revenues were $71.5 million and $204.9 million for the fourth quarter and full year of 2023, representing year-over-year growth of 193% and 309%, respectively. Total product revenues for the comparable periods in 2022 were $24.4 million and $50.0 million, respectively. Total revenue for the full year of 2023 was $270.6 million, which includes license revenue of $65.7 million from out-licensing Sunosi® in certain ex-U.S. territories.
- Auvelity® net product sales were $49.0 million and $130.1 million for the fourth quarter and full year of 2023, the first full year of launch. Auvelity was launched on October 19, 2022, and had U.S. net sales of $5.2 million for the fourth quarter of 2022.
- Sunosi net product revenues were $22.5 million and $74.8 million for the fourth quarter and full year of 2023, representing 17% and 67% year-over-year growth, respectively, consisting of $21.7 million and $72.4 million in net product sales and $0.8 million and $2.4 million in royalty revenue associated with Sunosi sales in out-licensed territories, respectively. Sunosi net sales for the comparable periods in 2022 were $19.2 million and $44.9 million, respectively. The U.S. portion of the acquisition of Sunosi closed in May 2022 and the ex-U.S. portion closed in November of 2022. Total Sunosi revenue for the full year of 2023 was $140.5 million, which includes license revenue of $65.7 million from out-licensing Sunosi in certain ex-U.S. territories.
- Total costs of revenue were $7.4 million and $26.1 million for the fourth quarter and full year of 2023, respectively. Total costs of revenue for the comparable periods in 2022 was $2.3 million and $5.2 million, respectively. Total cost of revenue for the full year of 2023 included a one-time cost of $5.0 million associated with the upfront fee received for the Sunosi out licensing transaction.
- Research and development (R&D) expenses were $30.8 million and $97.9 million for the fourth quarter and full year of 2023, respectively, compared to $14.7 million and $57.9 million for the comparable periods in 2022, respectively. The

increase was primarily related to the FOCUS trial of solriamfetol in ADHD, the advancement of ongoing trials of AXS-05 and AXS-12, manufacturing costs 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 $86.8 million and $323.1 million for the fourth quarter and full year of 2023, respectively, compared to $61.5 million and $159.3 million for the comparable periods in 2022, respectively. The increase was primarily related to commercialization activities for Auvelity and Sunosi, including sales force and marketing expenses, and higher personnel costs related to organizational growth, including non-cash stock-based compensation.
- Net loss for the fourth quarter of 2023 was $98.7 million or $(2.08) per share, compared to a net loss of $61.2 million, or $(1.41) per share, for the comparable period in 2022. The net loss in the fourth quarter of 2023 includes $63.7 million in non-cash charges, comprised of $43.2 million in acquisition-related contingent consideration expense reflecting updated sales projections for the recently announced new indications in solriamfetol, $18.9 million of non-cash stock-based compensation expense, and $1.6 million of non-cash intangible asset amortization. Net loss was $239.2 million, or $(5.27) per share, for the full year of 2023, compared to a net loss of $187.1 million, or $(4.60) per share, for the full year of 2022. The net loss for the full year includes total non-cash charges of $117.9 million which includes $62.6 million of stock-based compensation expense, $48.9 million in fair value of contingent consideration expense, and $6.4 million in intangible amortization compared to $37.7 million, $3.3 million, and $4.1 million respectively for the full year 2022.
- Cash and cash equivalents totaled $386.2 million at December 31, 2023, compared to $200.8 million at December 31, 2022.
- Shares of common stock outstanding were 47,351,363 at December 31, 2023.

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 84,000 prescriptions were written for Auvelity in the fourth quarter of 2023, representing a 23% sequential increase versus the third quarter of 2023.
- The previously announced expansion of the Auvelity neuropsychiatry sales force from 162 to 260 representatives is now complete. The sales force expansion along with Axsome's pioneering, technology-driven Digital Centric Commercialization (DCC™) platform is expected to increase our reach to approximately 44,000 health care providers, who write nearly 90% of new branded antidepressant prescriptions.
- Payer coverage for Auvelity across all channels is stable at approximately 70% of all covered lives. Commercial coverage is at approximately 48%, and Auvelity is a protected class product which must be covered by all payors in the Medicare channel and is covered by all state Medicaid programs. Axsome expects coverage to continue to expand and evolve.

Sunosi

- Approximately 42,000 prescriptions were written for Sunosi in the U.S. in the fourth quarter of 2023, representing an 18% increase versus the fourth quarter of 2022 and a 2% sequential increase versus the third 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:** 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 anticipated enrollment trends and recent changes to treatment market dynamics, the Company now anticipates completion of ADVANCE-2 in the second half of 2024.

- **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:** Manufacturing activities related to the planned resubmission of the New Drug Application (NDA) for AXS-07 for the acute treatment of migraine continue to progress. The Company continues to anticipate resubmission of the NDA in the first half 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.

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:** Enrollment in the SYMPHONY study, a Phase 3 randomized, multicenter, double-blind, placebo-controlled, parallel-group trial of AXS-12 in the treatment of narcolepsy has been completed. The Company is on track to announce topline results for SYMPHONY in the first quarter of 2024.

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:** Axsome is compiling the NDA for AXS-14 for the management of fibromyalgia. The Company is on track to submit the NDA in the first half 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 trial in the second half of 2024.
- **Major Depressive Disorder:** The Company plans to initiate a Phase 3 trial of solriamfetol for the treatment of MDD in the first quarter of 2024.
- **Binge Eating Disorder:** The Company plans to initiate a Phase 3 trial of solriamfetol for the treatment of BED in the first quarter of 2024.
- **Shift Work Disorder:** The Company plans to initiate a Phase 3 trial of solriamfetol for the treatment of excessive sleepiness (ES) associated with SWD in the first quarter of 2024.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-07 for migraine, NDA resubmission (1H 2024)
  - AXS-14 for fibromyalgia, NDA submission (1H 2024)
- **Clinical Trial Topline Results:**
  - Phase 3 SYMPHONY trial of AXS-12 in narcolepsy (1Q 2024)
  - Phase 3 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (2H 2024)
  - Phase 3 FOCUS trial of solriamfetol in attention deficit hyperactivity disorder (ADHD) in adults (2H 2024)
- **Clinical Trial Initiations:**
  - Phase 3 trial of solriamfetol in major depressive disorder (MDD) (1Q 2024)
  - Phase 3 trial of solriamfetol for binge eating disorder (BED) (1Q 2024)
  - Phase 3 trial of solriamfetol in shift work disorder (SWD) (1Q 2024)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation (2024)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss fourth quarter and full year 2023 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
(Unaudited, in thousands, except for share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 386,193	$ 200,842
Accounts receivables, net	94,820	37,699
Inventories, net	15,135	4,320
Prepaid and other current assets	8,115	2,781
Total current assets	504,263	245,642
Equipment, net	846	722
Right-of-use asset - operating lease	6,772	420
Goodwill	12,042	10,310
Intangible asset, net	53,286	59,661
Non-current inventory and other assets	11,027	14,721
Total assets	$ 588,236	$ 331,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 40,679	$ 38,605
Accrued expenses and other current liabilities	90,501	51,631
Operating lease liability, current portion	1,267	425
Contingent consideration, current	6,407	5,900
Total current liabilities	138,854	96,561
Contingent consideration, non-current	73,300	31,100

Loan payable, long-term	178,070	94,259
Operating lease liability, long-term	7,035	—
Total liabilities	397,259	221,920
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, 47,351,363 and 43,498,617 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively)	5	4
Additional paid-in capital	1,026,543	705,885
Accumulated deficit	(835,571)	(596,333)
Total stockholders' equity	190,977	109,556
Total liabilities and stockholders' equity	$ 588,236	$ 331,476

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 70,747	$ 24,372	$ 202,460	$ 50,037
License revenue	—	—	65,735	—
Royalty revenue	784	—	2,405	—
Total revenues	71,531	24,372	270,600	50,037
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	7,377	2,291	26,065	5,198
Research and development	30,803	14,693	97,944	57,947
Selling, general and administrative	86,810	61,498	323,123	159,254
Loss in fair value of contingent consideration	43,207	4,200	48,918	3,298
Intangible asset amortization	1,607	1,607	6,375	4,139
Total operating expenses	169,804	84,289	502,425	229,836
Loss from operations	(98,273)	(59,917)	(231,825)	(179,799)
Interest expense, net	(703)	(1,323)	(6,453)	(7,335)
Loss before income taxes	(98,976)	(61,240)	(238,278)	(187,134)
Income tax benefit (expense)	325	—	(960)	—
Net loss	$ (98,651)	$ (61,240)	$ (239,238)	$ (187,134)
Net loss per common share, basic and diluted	$ (2.08)	$ (1.41)	$ (5.27)	$ (4.60)
Weighted average common shares outstanding, basic and diluted	47,329,782	43,447,309	45,425,212	40,655,941

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

Source: Axsome Therapeutics, Inc.