Axsome Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

November 6, 2023

Total 3Q 2023 product revenue of $57.8 million, representing 244% year-over-year growth

Auvelity® 3Q 2023 net product sales of $37.7 million, representing 36% quarter-over-quarter growth

Sunosi® 3Q 2023 net product revenue of $20.1 million, representing 20% year-over-year growth

SYMPHONY Phase 3 trial of AXS-12 in narcolepsy on track for completion of enrollment in 4Q 2023; topline results expected in 1Q 2024

Phase 3 trial of solriamfetol in binge eating disorder on track for initiation in 4Q 2023

Phase 3 trial of solriamfetol in shift work disorder on track for initiation in 1Q 2024

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

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

NEW YORK, Nov. 06, 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 third quarter ended September 30, 2023.

“Results for the third quarter evidenced significant revenue momentum for Axsome driven by solid performance from both Auvelity and Sunosi. This positive trajectory will be further enhanced by our Auvelity field force expansion, which is expected to be fully implemented by the first quarter,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “We also progressed our extensive and innovative neuroscience pipeline in the quarter, enabling Axsome to potentially execute on numerous important clinical and regulatory milestones over the next 12 months, including multiple potential NDA submissions, and multiple pivotal trial readouts and initiations in new indications. The advancement of our commercial portfolio and clinical programs positions us well to continue to deliver potentially life-changing new medicines to patients with serious brain disorders, and to their health care providers.”

Third Quarter 2023 Financial Highlights

- Total product revenue for the third quarter of 2023 was $57.8 million, representing 244% year-over-year growth, and consisting of net product sales of $57.1 million and royalty revenue of $0.7 million. Total product revenue for the comparable period in 2022 was $16.8 million.
- Auvelity® net product sales were $37.7 million for the third quarter of 2023, representing a 36% sequential increase versus the second quarter of 2023. There were no Auvelity sales in the comparable 2022 period as the product was launched in October 2022.
- Sunosi® net product revenue was $20.1 million for the third quarter of 2023, representing 20% year-over-year growth, and consisting of $19.4 million in net product sales and $0.7 million in royalty revenue associated with Sunosi sales in out-licensed territories. Sunosi net product revenue for the comparable period in 2022 was $16.8 million.
- Total cost of revenue was $6.5 million for the third quarter of 2023. Total cost of revenue for the comparable period in 2022 was $1.9 million.
- Research and development (R&D) expenses were $28.8 million for the third quarter of 2023, compared to $14.9 million for the comparable period in 2022. The increase was primarily related to the FOCUS trial of solriamfetol in ADHD, the advancement of ongoing trials of AXS-05 and AXS-12, CMC 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 $83.2 million for the third quarter of 2023, compared to $40.9 million for the comparable period in 2022. The increase was primarily related to commercial activities for Auvelity and Sunosi, and higher personnel costs related to organizational growth, including non-cash stock-based compensation.

- Net loss for the third quarter of 2023 was $62.2 million or $(1.32) per share, compared to a net loss of $44.8 million, or $(1.07) per share, for the comparable period in 2022. The net loss in the third quarter of 2023 reflects $18.0 million in non-cash charges, comprised of $16.4 million of non-cash stock-based compensation expense, and $1.6 million of non-cash intangible asset amortization, partially offset by a $0.2 million of non-cash fair value remeasurement gain in contingent consideration.

- Cash and cash equivalents totaled $416.6 million at September 30, 2023, compared to $200.8 million at December 31, 2022.

- Shares of common stock outstanding were 47,317,381 at September 30, 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 69,000 prescriptions were reported for Auvelity in the third quarter of 2023, representing a 30% sequential increase versus the second quarter of 2023.

- The previously announced expansion of the Auvelity sales force from 162 to 260 representatives is underway and expected to be completed in the fourth quarter of 2023. The expansion will allow for greater reach and call frequency to target health care providers, potentially significantly broadening the prescriber base for Auvelity. The increased number of representatives together with Axsome's innovative Digital Centric Commercialization (DCC™) platform is expected to increase our reach from approximately 26,000 to approximately 44,000 physicians who write approximately 90% of new branded antidepressant prescriptions.

- Payer coverage for Auvelity across all channels is currently at approximately 70% of all covered lives. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 48% and approximately 100%, respectively. Active discussions with payers continue as coverage further expands and evolves.

Sunosi

- Third quarter 2023 U.S. Sunosi total prescriptions increased by 16% versus the third quarter of 2022, and sequentially by 5% versus the second 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 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 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 current enrollment trends, the Company continues to anticipate completion of ADVANCE-2 in the first 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:** 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. The Company is on track to complete enrollment in the SYMPHONY trial in the fourth quarter of 2023, with announcement of topline results anticipated in the first quarter of 2024.

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:** Pre-submission activities related to the planned submission of an NDA to the FDA for AXS-14 for the management of fibromyalgia are ongoing. The Company expects to submit the NDA in the first 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 in development for the treatment of attention deficit hyperactivity disorder (ADHD), 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.

- **Binge Eating Disorder:** The Company previously received positive pre-IND meeting feedback from the FDA on the development of solriamfetol for the treatment of BED and is on track to initiate a Phase 3 trial in the fourth quarter of 2023. BED is the most common eating disorder, affecting an estimated 2.8% of U.S. adults.[1] Treatment options are limited with only one product currently approved for the treatment of BED.

- **Shift Work Disorder:** Axsome previously received positive pre-IND meeting feedback from the FDA on the development of solriamfetol for the treatment of excessive sleepiness (ES) associated with SWD, a potentially new indication for solriamfetol and is on track to initiate a Phase 3 trial in patients with ES associated with SWD in the first quarter of 2024. An estimated one third of Americans perform shift work, of whom 10-43% are diagnosed with SWD.[2-4] Treatment options are limited with only two products currently approved for the treatment of ES associated with SWD.

Corporate Update

- In October 2023, Axsome announced the appointment of Susan Mahony, PhD, to its board of directors. Dr. Mahony most recently served on the board of directors of Horizon Therapeutics from 2019 until its acquisition by Amgen in October 2023. She was formerly Senior Vice President of Eli Lilly and Company and President of Lilly Oncology.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-07 for migraine, NDA resubmission (1H 2024)
  - AXS-14 for fibromyalgia, NDA submission (1Q 2024)
- **Clinical Trial 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 (1H 2024)
  - Phase 3 FOCUS trial of solriamfetol in ADHD in adults (2H 2024)
- **Clinical Trial Initiations:**

- Phase 3 trial of solriamfetol for BED (4Q 2023)
- Phase 3 trial of solriamfetol in 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 third quarter 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 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
(In thousands, except for share and par value amounts)

	September 30, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 416,564	$ 200,842
Accounts receivables, net	78,415	37,699
Inventories, net	9,985	4,320
Prepaid and other current assets	6,799	2,781
Total current assets	511,763	245,642
Equipment, net	971	722
Right-of-use asset - operating lease	7,068	420
Goodwill	12,042	10,310
Intangible asset, net	54,893	59,661
Non-current inventory and other assets	14,120	14,721

Total assets	$ 600,857	$ 331,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 29,098	$ 38,605
Accrued expenses and other current liabilities	78,454	51,631
Operating lease liability, current portion	438	425
Contingent consideration, current	6,672	5,900
Total current liabilities	114,662	96,561
Contingent consideration, non-current	31,550	31,100
Loan payable, long-term	177,446	94,259
Operating lease liability, long-term	7,691	—
Total liabilities	331,349	221,920
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at September 30, 2023 and December 31, 2022, respectively)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 47,317,381 and 43,498,617 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively)	5	4
Additional paid-in capital	1,006,423	705,885
Accumulated deficit	(736,920)	(596,333)
Total stockholders' equity	269,508	109,556
Total liabilities and stockholders' equity	$ 600,857	$ 331,476

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 57,127	$ 16,846	$ 131,713	$ 25,666
License revenue	—	—	65,735	—
Royalty revenue	667	—	1,622	—
Total Revenues	57,794	16,846	199,070	25,666
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	6,532	1,924	18,687	2,907
Research and development	28,767	14,877	67,141	43,254
Selling, general and administrative	83,188	40,892	236,314	97,756
Loss (Gain) in fair value of contingent consideration	(180)	(42)	5,711	(902)
Intangible asset amortization	1,607	1,607	4,768	2,532
Total operating expenses	119,914	59,258	332,621	145,547
Loss from operations	(62,120)	(42,412)	(133,551)	(119,881)
Interest expense, net	(757)	(2,411)	(5,751)	(6,012)
Loss before income taxes	(62,877)	(44,823)	(139,302)	(125,893)
Income tax benefit (expense)	678	—	(1,285)	—
Net loss	$ (62,199)	$ (44,823)	$ (140,587)	$ (125,893)
Net loss per common share, basic and diluted	$ (1.32)	$ (1.07)	$ (3.14)	$ (3.17)
Weighted average common shares outstanding, basic and diluted	47,117,196	41,704,362	44,783,380	39,715,261

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

References:

1. J. I. Hudson, E. Hiripi, H. G. Pope, and R. C. Kessler, “The Prevalence and Correlates of Eating Disorders in the National Comorbidity Survey Replication,” Biol. Psychiatry, vol. 61, no. 3, pp. 348–358, Feb. 2007, doi: 10.1016/j.biopsych.2006.03.040.
2. Alterman, T., Luckhaupt, S. E., Dahlhamer, J. M., Ward, B. W. & Calvert, G. M. Prevalence rates of work organization characteristics among workers in the U.S.: data from the 2010 National Health Interview Survey. Am. J. Ind. Med. 56, 647–659 (2013).
3. Drake, C. L., Roehrs, T., Richardson, G., Walsh, J. K. & Roth, T. Shift work sleep disorder: prevalence and consequences beyond that of symptomatic day workers. Sleep 27, 1453–1462 (2004).
4. Wickwire, E. M., Geiger-Brown, J., Scharf, S. M. & Drake, C. L. Shift Work and Shift Work Sleep Disorder: Clinical and Organizational Perspectives. Chest 151, 1156–1172 (2017).

Source: Axsome Therapeutics, Inc.