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

August 7, 2023

Total 2Q 2023 product revenue of $46.7 million

Auvelity® 2Q 2023 net product sales of $27.6 million, representing 76% quarter-over-quarter growth

Sunosi® 2Q 2023 net product revenue of $19.1 million

Pro forma second quarter cash balance of $468.8 million

FOCUS Phase 3 trial of solriamfetol in attention-deficit hyperactivity disorder initiated

Positive FDA pre-IND meeting feedback received for two new potential indications for solriamfetol: Phase 3 trial initiations planned for binge eating disorder in 4Q 2023, and shift work disorder in 1Q 2024

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

NEW YORK, Aug. 07, 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 second quarter ended June 30, 2023.

"We exhibited strong financial performance and pipeline advancement in the second quarter. Given the positive reception to date from clinicians to the Auvelity launch, we are expanding the Auvelity sales force by approximately 100 representatives. The expansion combined with our innovative DCC approach is expected to significantly increase our reach from approximately 26,000 to 44,000 physicians who write greater than 80% of branded antidepressant prescriptions," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Our Q2 relaunch of Sunosi is also well underway, and we are seeing positive results from these efforts. Our late-stage CNS pipeline continues to expand, and we are pleased to announce the launch of three new high value potential indications for solriamfetol: ADHD, for which we recently initiated the FOCUS Phase 3 trial, and binge eating disorder and shift work disorder for which we intend to initiate Phase 3 trials over the next two quarters based on positive FDA feedback on their development plans. We also look forward to topline results from the SYMPHONY Phase 3 trial of AXS-12 in narcolepsy and the ADVANCE-2 Phase 3 trial of AXS-05 in Alzheimer's disease agitation, which remain on track. Following our recent public offering of common stock, we are solidly positioned to further build value across our commercial and development portfolio."

Second Quarter 2023 Financial Highlights

- Total product revenue for the second quarter of 2023 was $46.7 million, consisting of net product sales of $46.0 million and royalty revenue of $0.7 million. Total product revenue for the comparable period in 2022 was $8.8 million.
- Auvelity® net product sales were $27.6 million for the second quarter of 2023, representing a 76% sequential increase versus the first 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 $19.1 million for the second quarter of 2023, consisting of $18.4 million in net product sales and $0.7 million in royalty revenue associated with Sunosi sales in out-licensed territories. Sunosi revenue to Axsome for the comparable period in 2022 was $8.8 million.
- Total cost of revenue was $4.6 million for the second quarter of 2023. Total cost of revenue for the comparable period in 2022 was $1.0 million.
- Research and development (R&D) expenses were $20.6 million for the second quarter of 2023, compared to $15.8 million for the comparable period in 2022. The increase was primarily related to the initiation of the FOCUS trial of solriamfetol in ADHD, the advancement of ongoing trials of AXS-05 and AXS-12, 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 $78.9 million for the second quarter of 2023, compared to $31.2 million for the comparable period in 2022. The increase was primarily related to the commercialization of Auvelity

and Sunosi, and higher personnel costs related to organizational growth, including non-cash stock-based compensation.

- Net loss for the second quarter of 2023 was $67.2 million or $(1.54) per share, compared to a net loss of $41.4 million, or $(1.06) per share, for the comparable period in 2022. The net loss in the second quarter of 2023 reflects $23.6 million in non-cash charges, comprised of $15.9 million of non-cash stock-based compensation expense, $6.1 million of non-cash loss in fair value of contingent consideration, and $1.6 million of non-cash intangible asset amortization.

- In June 2023, Axsome completed an underwritten public offering of common stock resulting in gross proceeds of $225 million. Subsequently, in July 2023, the underwriters exercised their option to purchase an additional 15% of common stock in connection with the public offering (the “green shoe”), resulting in additional gross proceeds to Axsome of $33.8 million.

- Cash and cash equivalents totaled $437.1 million at June 30, 2023, compared to $200.8 million at December 31, 2022. The cash balance includes net proceeds from the June 2023 common stock offering and does not reflect the subsequent green shoe exercise. Pro forma cash at June 30, 2023, inclusive of net proceeds from the green shoe, totaled $468.8 million.

- Shares of common stock outstanding were 46,726,794 at June 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 53,000 prescriptions were reported for Auvelity in the second quarter of 2023, representing a 72% sequential increase versus the first quarter of 2023.

- Based on the initial positive market reception to the Auvelity launch, Axsome is expanding the Auvelity sales force from 162 to 260 representatives. The expansion will allow for greater reach and call frequency to target physicians, potentially significantly broadening the prescriber base for Auvelity. The increased number of representatives together with our innovative Digital Centric Commercialization (DCC™) platform is expected to increase our reach from approximately 26,000 to approximately 44,000 physicians who write greater than 80% of branded antidepressant prescriptions.

- Payer coverage for Auvelity across all channels is currently at approximately 68% of all covered lives. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 46% and approximately 100%, respectively. Interactions with payers are ongoing as coverage expansion continues.

Sunosi

- Second quarter 2023 U.S. Sunosi total prescriptions increased by 15% versus the second quarter of 2022, and sequentially by 8% versus the first 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 proceed to a pivotal Phase 2/3 trial in this indication. The Company anticipates initiation of this study in the fourth quarter of 2023 or the first quarter of 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 are progressing. The Company now anticipates 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 anticipates completion of the SYMPHONY trial in the fourth quarter 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 now expects to submit the NDA in the fourth quarter of 2023 or 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:** In July 2023, Axsome initiated 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. An estimated 11.4 million adults in the U.S. are diagnosed with ADHD, and the condition affects an estimated 5% of children and adolescents.[1,2] The disease burden for ADHD is high, with total annual societal excess costs estimated at $122.8 billion for adult ADHD in the U.S.[3] The Company anticipates topline results from the FOCUS trial in the second half of 2024.

- **Binge Eating Disorder:** Axsome recently received positive pre-IND meeting feedback from the FDA on the development of solriamfetol for the treatment of BED, a potentially new indication for solriamfetol. BED is the most common eating disorder, affecting an estimated 2.8% of U.S. adults.[4] Treatment options are limited with only one product currently approved for the treatment of BED. Based on the FDA's feedback, the Company is preparing to initiate a Phase 3 trial of solriamfetol in patients with BED in the fourth quarter of 2023.

- **Shift Work Disorder:** Axsome recently 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. An estimated one third of Americans perform shift work, of whom 10-43% are diagnosed with SWD.[5-7] Treatment options are limited with only two products currently approved for the treatment of ES associated with SWD. Based on the FDA's feedback, the Company is preparing to initiate a Phase 3 trial of solriamfetol in patients with 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 (4Q 2023 – 1Q 2024)
- **Clinical Trial Readouts:**
  - Phase 3 SYMPHONY trial of AXS-12 in narcolepsy (4Q 2023)
  - 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 binge eating disorder (4Q 2023)
  - Phase 3 trial of solriamfetol in shift work disorder (1Q 2024)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation (4Q 2023 – 1Q 2024)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss first 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)

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 437,113	$ 200,842
Accounts receivables, net	67,410	37,699
Inventories, net	9,252	4,320
Prepaid and other current assets	5,911	2,781
Total current assets	519,686	245,642
Equipment, net	736	722

Right-of-use asset - operating lease	7,412	420
Goodwill	12,042	10,310
Intangible asset, net	56,500	59,661
Non-current inventory and other assets	15,262	14,721
Total assets	$ 611,638	$ 331,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 42,958	$ 38,605
Accrued expenses and other current liabilities	65,324	51,631
Operating lease liability, current portion	350	425
Contingent consideration, current	6,342	5,900
Total current liabilities	114,974	96,561
Contingent consideration, non-current	33,500	31,100
Loan payable, long-term	176,820	94,259
Operating lease liability, long-term	7,540	—
Total liabilities	332,834	221,920
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at June 30, 2023 and December 31, 2022, respectively)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 46,726,794 and 43,498,617 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively)	5	4
Additional paid-in capital	953,520	705,885
Accumulated deficit	(674,721)	(596,333)
Total stockholders' equity	278,804	109,556
Total liabilities and stockholders' equity	$ 611,638	$ 331,476

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 46,017	$ 8,820	$ 74,586	$ 8,820
License revenue	—	—	65,735	—
Royalty revenue	683	—	955	—
Total Revenues	46,700	8,820	141,276	8,820
Operating expenses:				
Cost of revenue (excluding amortization and depreciation)	4,599	983	12,155	983
Research and development	20,581	15,792	38,374	28,377
Selling, general and administrative	78,935	31,160	153,126	56,864
Loss (Gain) in fair value of contingent consideration	6,053	(860)	5,891	(860)
Intangible asset amortization	1,589	926	3,161	926
Total operating expenses	111,757	48,001	212,707	86,290
Loss from operations	(65,057)	(39,181)	(71,431)	(77,470)
Interest expense, net	(2,730)	(2,257)	(4,994)	(3,601)
Loss before income taxes	(67,787)	(41,438)	(76,425)	(81,071)
Income tax benefit (expense)	617	—	(1,963)	—
Net loss	$ (67,170)	$ (41,438)	$ (78,388)	$ (81,071)
Net loss per common share, basic and diluted	$ (1.54)	$ (1.06)	$ (1.80)	$ (2.09)
Weighted average common shares outstanding, basic and diluted	43,669,820	39,081,100	43,597,131	38,704,227

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

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Source: Axsome Therapeutics, Inc.