Axsome Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Update

November 7, 2022

Sunosi® third quarter U.S. net sales of $16.8 million

Auvelity™ launched and available in U.S. pharmacies

SHARP study results announced demonstrating statistically significant improvement in cognitive function with Sunosi versus placebo

ADVANCE-2 trial of AXS-05 in Alzheimer's disease agitation initiated

Successful Type A meeting completed for AXS-07 for the acute treatment of migraine

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

NEW YORK, Nov. 07, 2022 (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, 2022.

"Axsome's transformation into a commercial stage, fully integrated, research and development driven, CNS focused biopharmaceutical company has accelerated with the successful commercialization of Sunosi, and now the launch of Auvelity for the treatment of major depressive disorder in adults," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "While it is still extremely early days in the Auvelity launch, we are very encouraged by the interest and reception from the prescriber community thus far. Our first-in-class DCC, or digital centric commercialization, platform is already demonstrating the effectiveness and efficiency of a contemporary, integrated, omni-channel approach to meaningful customer engagements. In parallel with our commercial efforts, our industry leading neuroscience development pipeline is progressing, setting the stage for continued potentially significant value creation over the near, intermediate and long term. This late-stage portfolio comprises five differentiated, product candidates, including AXS-05 for Alzheimer's disease agitation and smoking cessation, solriamfetol for ADHD, AXS-12 for narcolepsy, and AXS-14 for fibromyalgia. We anticipate this portfolio to generate multiple clinical trial readouts, clinical trial initiations, and NDA filings over the remainder of this year and through 2023."

Third Quarter 2022 Financial Highlights

- Total revenues were $16.8 million for the third quarter of 2022, compared to none for the 2021 comparable period. U.S. net sales of Sunosi were $16.8 million for the third quarter of 2022. No Sunosi sales were reported by Axsome for the 2021 comparable period reflecting the timing of the Sunosi acquisition.
- Total cost of product sales were $1.9 million for the third quarter of 2022, compared to none for the 2021 comparable period.
- Research and development (R&D) expenses were $14.9 million for the third quarter of 2022 and $13.2 million for the comparable period in 2021. The increase was primarily related to higher costs associated with ongoing clinical trials, including post-marketing commitments assumed for Sunosi.
- Selling, general, and administrative (SG&A) expenses were $40.9 million for the third quarter of 2022 and $20.2 million for the comparable period in 2021. The increase was primarily related to commercial activities for Sunosi and Auvelity, including sales force onboarding and marketing spend, and higher non-cash stock compensation expense.
- Net loss was $44.8 million, or $(1.07) per share, for the third quarter of 2022, compared to a net loss of $34.9 million, or $(0.93) per share, for the comparable period in 2021. The net loss for the current period included $9.2 million of non-cash stock compensation expense compared to $5.7 million in the comparable period in 2021.
- Cash and cash equivalents totaled $227.5 million at September 30, 2022, compared to $86.5 million at December 31, 2021. During the quarter, the Company utilized its existing at-the-market equity facility and received net proceeds of $175 million.
- Shares of common stock outstanding were 43,425,709 at September 30, 2022.

Financial Guidance

- Axsome believes that its current cash, along with the remaining committed capital from the $300 million term loan facility, is sufficient to fund anticipated operations into 2025, 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

Sunosi

- Axsome's first full quarter of U.S. Sunosi commercialization was characterized by significantly increased sales force productivity aided by the Company's Digital Centric Commercialization™ (DDC) approach. Third quarter U.S. Sunosi total prescriptions increased by 15% versus the third quarter of 2021, and by 3% versus the second quarter of 2022.

- Sunosi has broad payer coverage in the commercial channel with 96% of lives covered. Currently 64% of lives are covered in the Medicare Part D and Medicaid channels.

- The ex-U.S. acquisition of Sunosi is on track to close in the fourth quarter of 2022.

Auvelity

- Axsome announced the commercial launch of Auvelity on October 20, 2022, following its approval by the FDA on August 18, 2022. Auvelity is currently available by prescription in the U.S.

- Our Auvelity field force is actively engaging healthcare providers to provide comprehensive education on Auvelity. The vast majority of our sales specialists have prior psychiatry experience. Successful early engagement with target prescribers is being achieved through remote and in-person interactions guided by our DCC platform. These activities are being accompanied by digital marketing, peer-to-peer medical education, and medical conference presence. Interactions with payers continue to be active and productive.

- Our comprehensive patient and provider support services are fully operational and performing as planned. These include the Auvelity Savings Card to reduce out-of-pocket expenses for qualifying patients, the Auvelity on My Side program, telehealth services, samples program, and payer assistance to help clinicians provide their patients access to Auvelity.

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 the 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 September 2022, Axsome initiated the ADVANCE-2 study, a Phase 3, randomized, double-blind, placebo-controlled, multicenter, trial to assess the efficacy and safety of AXS-05 for the treatment of agitation associated with AD. Concurrent with the initiation of ADVANCE-2, the Company has concluded the ACCORD randomized withdrawal trial. Topline results from ACCORD are on track for the fourth quarter of 2022.

- **Smoking Cessation:** Axsome plans to proceed to a pivotal Phase 2/3 trial in this indication. The Company intends to provide information on the timing of initiation of this study in 2022.

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:** Axsome held a Type A meeting with the FDA in the third quarter to discuss the Company's approach to its planned resubmission of the New Drug Application (NDA) for AXS-07 for the acute treatment of migraine. Following the meeting, the Company intends to resubmit its NDA in the third quarter 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 2/3 multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of solriamfetol in adults with ADHD in the fourth quarter of 2022.

- **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.

- **New mechanism of action data:** New preclinical pharmacology studies have identified agonist activity at the trace amine-associated receptor 1 (TAAR1) and lower potency agonist activity at 5-HT1A receptors for solriamfetol, in addition to its activity as a dopamine and norepinephrine reuptake inhibitor (DNRI). These findings were presented at the 2022 Psych Congress in September. TAAR1 is a G-protein coupled receptor with affinity for the trace amines, and TAAR1 agonists have demonstrated pro-cognitive and wake-promoting effects in rodents and primates.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-07 for migraine, NDA resubmission (3Q 2023)
  - AXS-14 for fibromyalgia, NDA submission (2023)
- **Clinical Trial Readouts:**
  - Phase 3 ACCORD trial of AXS-05 for Alzheimer's disease agitation, topline data (4Q 2022)
  - 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 (2025)
- **Clinical Trial Initiations:**
  - Phase 2/3 trial of solriamfetol for ADHD in adults (4Q 2022)

Conference Call Information

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

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 227,520,218	$ 86,472,854
Accounts receivables, net	20,302,222	—
Inventories, net	2,103,477	—
Prepaid and other current assets	2,457,513	45,286
Total current assets	252,383,430	86,518,140
Equipment, net	626,990	283,846
Right-of-use asset - operating lease	384,568	660,162
Goodwill	11,897,000	—
Intangible asset, net	61,267,561	—
Non-current inventory and other assets	12,398,220	322,910
Total assets	$ 338,957,769	$ 87,785,058
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 12,844,629	$ 13,149,329
Accrued expenses and other current liabilities	40,021,759	9,295,180
Operating lease liability, current portion	416,876	620,675
Contingent consideration, current	7,000,000	—
Total current liabilities	60,283,264	23,065,184
Contingent consideration, non-current	27,400,000	—
Loan payable, long-term	93,913,159	49,089,522
Total liabilities	181,596,423	72,154,706
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at September 30, 2022 and December 31, 2021, respectively)	—	—

Common stock, $0.0001 par value per share (150,000,000 shares authorized, 43,425,707 and 37,816,794 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively)	4,342	3,782
Additional paid-in capital	692,450,128	424,825,655
Accumulated deficit	(535,093,124)	(409,199,085)
Total stockholders' equity	157,361,346	15,630,352
Total liabilities and stockholders' equity	$ 338,957,769	$ 87,785,058

Axsome Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,	
	2022	**2021**
Revenues:		
Product sales, net	$ 16,845,792	$ —
Operating expenses:		
Cost of product sales (excluding amortization and depreciation)	1,923,831	—
Research and development	14,877,021	13,180,258
Selling, general and administrative	40,892,443	20,226,884
Gain in fair value of contingent consideration	(42,120)	—
Intangible asset amortization	1,606,789	—
Total operating expenses	59,257,964	33,407,142
Loss from operations	(42,412,172)	(33,407,142)
Interest expense, net	(2,411,040)	(1,475,535)
Net loss	$ (44,823,212)	$ (34,882,677)
Net loss per common share, basic and diluted	$ (1.07)	$ (0.93)
Weighted average common shares outstanding, basic and diluted	41,704,362	37,680,966

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