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

August 9, 2022

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

NEW YORK, Aug. 09, 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 second quarter ended June 30, 2022.

"We are very pleased to report our first commercial sales following the closing of the Sunosi acquisition in the second quarter. The rest of the year promises to continue to be eventful with the pending FDA action on our NDA for AXS-05 in major depressive disorder, and a Type A FDA meeting to discuss our planned resubmission of the NDA for AXS-07 in migraine, both anticipated this quarter," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Thus far, our commercial infrastructure is performing as planned positioning us well for a launch of AXS-05, should it be approved. In addition to our commercial- and NDA-stage portfolio, we continue to advance our leading development pipeline of Phase 3-stage product candidates and clinical programs, including AXS-05 for Alzheimer's disease agitation and smoking cessation, AXS-12 for narcolepsy, AXS-14 for fibromyalgia, and recently introduced solriamfetol for ADHD."

Business Update

Axsome is committed to developing and delivering medicines that meaningfully improve the lives of patients living with CNS disorders. The Company is advancing a broad portfolio of differentiated, patent-protected, CNS products and product candidates.

Commercial Product

Sunosi®

Sunosi (solriamfetol) is Axsome's dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA).

- Axsome completed its U.S. acquisition of Sunosi from Jazz Pharmaceuticals on May 9, 2022. The ex-U.S. transaction is now expected to close in the fourth quarter of 2022.
- Axsome generated approximately $8.8 million in U.S. net sales of Sunosi from May 9 to June 30, 2022.

Development Pipeline

Axsome is advancing a portfolio of differentiated, patent-protected, CNS product candidates with five in active clinical development.

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for the following indications: major depressive disorder (MDD), Alzheimer's disease (AD) agitation, and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designations for MDD and for AD agitation.

- **Depression:** Axsome's New Drug Application (NDA) for AXS-05 for the treatment of MDD was granted Priority Review and is currently under review by the FDA. The Company previously disclosed that it had entered into labeling discussions with the FDA on the NDA. Based on this interaction, the Company anticipates potential FDA action on the NDA in the third quarter of 2022.
- **Alzheimer's Disease Agitation:** Axsome has amended the relapse criteria for the ACCORD Phase 3 randomized withdrawal study of AXS-05 in AD agitation, informed by results of an analysis requested by the FDA of data from the previously completed positive ADVANCE-1 trial. To generate additional data to support the efficacy of AXS-05 in this indication, Axsome is initiating a new randomized, placebo-controlled parallel group trial (ADVANCE-2) this quarter. Concurrent with the initiation of ADVANCE-2, the Company is concluding the ACCORD randomized withdrawal trial. Topline results from ACCORD are now anticipated in 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:** Following the previously disclosed Complete Response Letter to the Company's NDA for AXS-07 for the acute treatment of migraine, Axsome recently submitted for a Type A meeting with the FDA to discuss the Company's approach to its planned resubmission of the NDA. The Company anticipates that this meeting will occur in the third quarter of 2022.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, and 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 are anticipated in the first half of 2023.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, and 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:** Axsome announced its plans to develop solriamfetol for the treatment of ADHD. The Company anticipates initiating 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 this year.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-05 for MDD, FDA action on NDA (3Q 2022)
  - AXS-05 for MDD, commercial launch, if approved (4Q 2022)
  - AXS-07 for migraine, Type A meeting (3Q 2022)
  - AXS-07 for migraine, NDA resubmission
  - 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)
- **Clinical Trial Initiations:**
  - Phase 3 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (3Q 2022)

- Phase 2/3 trial of solriamfetol for ADHD in adults (4Q 2022)

Second Quarter 2022 Financial Results

- **Revenue:** The Company recorded U.S. net sales of Sunosi from the May 9, 2022 acquisition date through the end of the second quarter 2022 of approximately $8.8 million. No net product sales were reported for the 2021 comparable period.
- **Research and development (R&D) expenses:** R&D expenses were $15.8 million for the three months ended June 30, 2022 and $14.5 million for the comparable period in 2021. The increase was driven by personnel expense and costs associated with ongoing clinical trials.
- **Selling, general, and administrative (SG&A) expenses:** SG&A expenses were $31.2 million for the three months ended June 30, 2022 and $16.3 million for the comparable period in 2021. The increase was primarily related to commercial activities for Sunosi, pre-commercial activities for our late-stage pipeline assets, and personnel expense, along with an increase in non-cash stock compensation expense.
- **Net loss:** Net loss was $41.4 million, or $(1.06) per share, for the three months ended June 30, 2022 compared to a net loss of $32.3 million, or $(0.86) per share, for the comparable period in 2021. The net loss for the current period included $10.2 million of non-cash stock compensation expense compared to $5.5 million in the comparable period in 2021.
- **Cash:** At June 30, 2022, Axsome had $73.4 million of cash compared to $86.5 million at December 31, 2021. Including proceeds from recent use of the Company's at-the-market equity facility and proceeds from operations, Axsome's pro-forma cash balance is $102 million.
- **Shares outstanding:** At June 30, 2022, Axsome had 39,914,411 shares of common stock outstanding.
- **Acquisition of Sunosi:** The preliminary accounting of the acquisition of Sunosi is included in our Q2 2022 financial statements. To date, we have performed a preliminary fair value analysis of the business combination. The final determination of these fair values will be completed within one year from the acquisition date.

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 2024, based on the current operating plan, which includes the commercialization of Sunosi and potential launch of AXS-05 in MDD.
- Axsome expects that its operating expenses will increase year over year as it continues to build out the commercial function and further advance its pipeline.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss second 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® product and the success of our efforts to obtain any additional indication(s) with respect to Sunosi®; 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 (including, but not limited to, whether potential filing issues or

issues identified by FDA during the substantive review may impact the potential approvability of the Company's NDA submission for AXS-05 in MDD or the timing of such approval; 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 potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients); 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 product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the continued commercialization of Sunosi and for the Company's commercial launch of its 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

Statements of Operations Information:

	Three Months June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 8,819,786	$ —	$ 8,819,786	$ —
Operating expenses:				
Cost of product sales	982,836	—	982,836	—
Research and development	15,792,202	14,503,326	28,377,343	31,099,014
Selling, general and administrative	31,160,140	16,344,361	56,863,871	27,592,734
Gain in fair value of contingent consideration	(860,000)	—	(860,000)	—
Intangible asset amortization	925,650	—	925,650	—
Total operating expenses	48,000,828	30,847,687	86,289,700	58,691,748
Loss from operations	(39,181,042)	(30,847,687)	(77,469,914)	(58,691,748)
Interest income (expense)	(2,257,474)	(1,436,522)	(3,600,913)	(2,852,431)
Net loss	$ (41,438,516)	$ (32,284,209)	$ (81,070,827)	$ (61,544,179)
Net loss per common share, basic and diluted	$ (1.06)	$ (0.86)	$ (2.09)	$ (1.64)
Weighted average common shares outstanding, basic and diluted	39,081,100	37,595,069	38,704,227	37,512,716

Balance Sheet Information:

	June 30, 2022	**December 31, 2021**
Cash and cash equivalents	$ 73,394,640	$ 86,472,854
Accounts receivables, net	16,167,927	—
Inventories, net	10,323,746	—
Prepaid and other current assets	4,091,369	45,286
Total current assets	103,977,682	86,518,140
Goodwill	11,897,407	—
Intangible asset, net	62,874,350	—
Other Assets	1,809,657	1,266,918
Total assets	180,559,096	87,785,058
Accounts payable	19,430,961	13,149,329
Accrued expenses and other current liabilities	17,189,442	9,915,855
Contingent consideration, current	5,950,000	—
Total current liabilities	42,570,403	23,065,184
Contingent consideration, non-current	29,330,407	—
Loan payable, long-term	93,458,824	49,089,522
Total liabilities	165,359,634	72,154,706
Accumulated deficit	(490,269,912)	(409,199,085)
Stockholders' equity	$ 15,199,462	$ 15,630,352

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