Axsome Therapeutics Reports Second Quarter 2016 Financial Results

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NEW YORK, Aug. 09, 2016 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ:AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today reported financial results for the second quarter ended June 30, 2016.

“In the second quarter we continued to advance our three ongoing Phase 3 trials, and we expanded our late-stage pipeline with the receipt of positive FDA guidance on our development plans for AXS-05 in Alzheimer’s agitation,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics. “Based on this guidance, we look forward to filing an IND for a Phase 2/3 trial in this indication by year end.”

Second Quarter Highlights

- Received Pre-Investigational New Drug Application (Pre-IND) written guidance from the U.S. Food and Drug Administration (FDA) on AXS-05 for agitation in patients with Alzheimer’s disease.

- Received Fast Track designation from the FDA for AXS-02 for the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs).

- Added to the broad-market Russell 3000® and small-cap Russell 2000® Indexes, as part of the Russell U.S. Indexes annual reconstitution.

Second Quarter 2016 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $5.3 million for the quarter ended June 30, 2016 compared to $1.6 million for the comparable period in 2015. The increase in R&D expenses was primarily due to the conduct of our Phase 3 clinical trials in complex regional pain syndrome (the CREATE-1 Study), treatment resistant depression (the STRIDE-1 Study), and knee OA associated with BMLs (the COAST-1 Study).

- **General and administrative (G&A) expenses:** G&A expenses were $1.5 million for the quarter ended June 30, 2016 compared to $0.5 million for the comparable period in 2015. The increase in G&A expenses was primarily due to external fees associated with operating as a public company, as well as an increase in personnel costs and stock compensation expense.

- **Net loss:** Net loss was $6.8 million, or $(0.36) per share for the quarter ended June 30, 2016, compared to a net loss of $2.1 million, or $(0.19) per share for the quarter ended June 30, 2015.

- **Cash:** As of June 30, 2016, Axsome had $38.8 million of cash compared to $48.0 million of cash as of December 31, 2015. Axsome currently anticipates that its cash will be sufficient to fund its anticipated operations into the third quarter of 2017.

- **Shares outstanding:** At June 30, 2016, Axsome had 19,149,417 shares of common stock outstanding.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, including pain, for which there are limited existing treatment options. Axsome’s product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in Phase 3 trials in complex regional pain syndrome (CRPS) and knee osteoarthritis (OA) associated with bone marrow

lesions (BMLs) with an additional Phase 3 trial planned in chronic low back pain (CLBP) associated with Modic changes (MCs). AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), and a Phase 2/3 trial in agitation in patients with Alzheimer's disease (AD) is planned. AXS-02 and AXS-05 are investigational product candidates not approved by the FDA. For more information, please visit the company website at www.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 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 and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; 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; 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
(unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 5,298,060	$ 1,628,394	$ 9,824,312	$ 3,044,677
General and administrative	1,529,220	456,410	2,885,833	973,250
Total operating expenses	6,827,280	2,084,804	12,710,145	4,017,927
Loss from operations	(6,827,280)	(2,084,804)	(12,710,145)	(4,017,927)
Interest and other income (expense)	15,090	(211,062)	32,014	(339,843)
Change in fair value of warrant liability	—	16,572	—	17,442

Change in fair value of embedded derivative liabilities	—	149,900	—	70,800
Net loss	$ (6,812,190)	$ (2,129,394)	$ (12,678,131)	$ (4,269,528)
Net loss per common share – basic and diluted	$ (0.36)	$ (0.19)	$ (0.66)	$ (0.38)
Weighted average common shares outstanding – basic and diluted	19,149,417	11,108,144	19,149,417	11,108,144

Balance Sheet Information:

	June 30, 2016	**December 31, 2015***
	(unaudited)	
Cash	$ 38,751,750	$ 48,036,260
Total assets	40,007,913	49,076,156
Accumulated deficit	(33,117,929)	(20,439,798)
Stockholders' equity	$ 34,904,355	$ 46,444,261

*Condensed from audited financial statements.

Axsome Contact:
Mark Jacobson
Vice President, Operations
Axsome Therapeutics, Inc.
25 Broadway, 9th Floor
New York, NY 10004
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

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