

Axsome Therapeutics Reports Third Quarter 2016 Financial Results

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NEW YORK, Nov. 14, 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 third quarter ended September 30, 2016.

“We continued to advance our three Phase 3 trials during this quarter,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics. “We look forward to filing an IND for our planned Phase 2/3 trial of AXS-05 in agitation in patients with Alzheimer’s disease, and an IND for our planned Phase 3 trial of AXS-02 in chronic low back pain associated with Modic changes, both by year end.”

Third Quarter and Recent Corporate Highlights

- Active enrollment continued in our three ongoing Phase 3 trials: the CREATE-1 trial in complex regional pain syndrome (CRPS), the STRIDE-1 trial in treatment resistant depression, and the COAST-1 trial in knee osteoarthritis associated with bone marrow lesions. To date approximately 40 subjects have been enrolled in CREATE-1 and the study currently has 45 activated sites. CREATE-1 incorporates an interim efficacy analysis that is triggered when approximately 95 enrolled subjects complete the double-blind portion of the trial. Based upon current trends, we anticipate reaching this enrollment target in the first or second quarter of 2017.
- In October 2016, results of a nonclinical study of AXS-02 in a well-validated animal model of CRPS were published in *Anesthesia & Analgesia*, a peer-reviewed journal. The results showed that in this model, AXS-02 completely reversed established pain and improved function.
- In November 2016, we entered into a \$20 million term loan agreement with Silicon Valley Bank. We have drawn \$10 million of this amount and can draw the remaining \$10 million subject to the achievement of certain clinical and financial milestones. This financing strengthens our balance sheet ahead of potential clinical data releases, allows us to conduct our planned Phase 2/3 trial of AXS-05 in agitation in patients with Alzheimer’s disease, and extends our cash runway.

Third Quarter 2016 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were \$5.6 million for the quarter ended September 30, 2016 compared to \$1.5 million for the comparable period in 2015. The increase in R&D expenses was primarily due to the conduct of our CREATE-1, STRIDE-1, and COAST-1 Phase 3 clinical trials.
- **General and administrative (G&A) expenses:** G&A expenses were \$1.6 million for the quarter ended September 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 \$7.2 million, or \$(0.38) per share for the quarter ended September 30, 2016, compared to a net loss of \$4.6 million, or \$(0.41) per share for the comparable period in 2015.
- **Cash:** At September 30, 2016, Axsome had \$33.9 million of cash compared to \$48.0 million of cash at December 31, 2015. Axsome believes that its cash at September 30, 2016, combined with the proceeds from the initial \$10 million tranche of the term loan with Silicon Valley Bank, will be sufficient to fund the company’s anticipated operations through the end of 2017.
- **Shares outstanding:** At September 30, 2016, Axsome had 19,153,417 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 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):

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Operating expenses:				
Research and development	\$ 5,568,777	\$ 1,524,395	\$ 15,393,089	\$ 4,569,072
General and administrative	1,639,026	499,421	4,524,859	1,472,671
Total operating expenses	7,207,803	2,023,816	19,917,948	6,041,743
Loss from operations	(7,207,803)	(2,023,816)	(19,917,948)	(6,041,743)
Interest and other income (expense)	13,219	(279,802)	45,233	(619,645)
Change in fair value of warrant liability	—	(32,005)	—	(14,563)

Change in fair value of embedded derivative liabilities	—	204,000	—	274,800
Loss on extinguishment of debt	—	(2,444,516)	—	(2,444,516)
Net loss	\$ (7,194,584)	\$ (4,576,139)	\$ (19,872,715)	\$ (8,845,667)
Net loss per common share – basic and diluted	\$ (0.38)	\$ (0.41)	\$ (1.04)	\$ (0.80)
Weighted average common shares outstanding – basic and diluted	19,149,906	11,108,144	19,149,579	11,108,144

Balance Sheet Information:

	<u>September 30, 2016</u> (unaudited)	<u>December 31, 2015*</u>
Cash	\$ 33,887,804	\$ 48,036,260
Total assets	34,918,454	49,076,156
Accumulated deficit	(40,312,513)	(20,439,798)
Stockholders' equity	\$ 28,182,918	\$ 46,444,261

*Condensed from audited financial statements.

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