Axsome Therapeutics Reports First Quarter 2016 Financial Results

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NEW YORK, May 11, 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 quarter ended March 31, 2016.

“We continued to make progress with our lead product candidates, AXS-02 and AXS-05, over the past quarter,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics. “We recently advanced AXS-02 into a registration trial in knee osteoarthritis associated with bone marrow lesions. We also received positive guidance from the FDA on our clinical development plans for AXS-05 in agitation in Alzheimer’s disease, which represents a second indication for this product candidate.”

First Quarter and Recent Corporate Highlights

- In May 2016, received from the U.S. Food and Drug Administration (FDA), Fast Track designation for AXS-02 for the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs).
- In April 2016, received from the FDA, Pre-Investigational New Drug Application (Pre-IND) written guidance on AXS-05 for agitation in patients with Alzheimer’s disease (AD).
- In March 2016, enrolled the first patient in the COAST-1 (Clinical Knee Osteoarthritis Symptom Treatment 1) study, a Phase 3 trial evaluating the efficacy and safety of AXS-02 for the pain of knee OA associated with BMLs.
- In March 2016, enrolled the first patient in the STRIDE-1 (Symptom Treatment in Resistant Depression 1) study, a Phase 3 trial evaluating the efficacy and safety of AXS-05 for treatment resistant depression (TRD).

First Quarter 2016 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $4.5 million for the quarter ended March 31, 2016 compared to $1.4 million for the comparable period in 2015. The increase in R&D expenses was primarily due to increased clinical trial expenses related to our CREATE-1, STRIDE-1, and COAST-1 studies, as well as an increase in personnel costs and stock compensation expense in 2016.
- **General and administrative (G&A) expenses:** G&A expenses were $1.4 million for the quarter ended March 31, 2016 compared to $0.5 million for the comparable period in 2015. The increase in G&A expenses was primarily due to fees incurred to support operating as a public company.
- **Net loss:** Net loss was $5.9 million, or $(0.31) per share for the quarter ended March 31, 2016, compared to a net loss of $2.1 million, or $(0.19) per share for the quarter ended March 31, 2015.
- **Cash:** As of March 31, 2016, Axsome had $44.1 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 March 31, 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 March 31,	
	2016	**2015**
Operating expenses:		
Research and development	$ 4,526,252	$ 1,416,283
General and administrative	1,356,613	516,840
Total operating expenses	5,882,865	1,933,123
Loss from operations	(5,882,865)	(1,933,123)
Interest and amortization of debt discount/premium income (expense)	16,924	(128,781)
Change in fair value of warrant liability	—	870
Change in fair value of embedded derivative liabilities	—	(79,100)
Net loss	$ (5,865,941)	$ (2,140,134)
Net loss per common share – basic and diluted	$ (0.31)	$ (0.19)
Weighted average common shares outstanding – basic and diluted	19,149,417	11,108,144

Balance Sheet Information:

	March 31, 2016	December 31, 2015*
	(unaudited)	
Cash	$ 44,078,000	$ 48,036,260
Total assets	45,148,244	49,076,156
Accumulated deficit	(24,654,739)	(18,788,798)
Stockholders' equity	$ 41,234,512	$ 46,444,261

*Condensed from audited financial statements.

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