

Axsome Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results

March 24, 2016 4:30 PM ET

NEW YORK, March 24, 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 fourth quarter and year ended December 31, 2015.

“2015 was a pivotal year for Axsome as we accomplished a number of important milestones including initiating our Phase 3 trial with AXS-02 in complex regional pain syndrome, as well as completing our initial public offering,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics.

“So far in 2016, we have advanced AXS-05, our second lead product candidate, into a registration trial in treatment resistant depression. AXS-05 is an innovative oral therapeutic, with activity at several key neurotransmitter systems, which we are developing for the treatment of CNS disorders. We look forward to continued progress with our other clinical programs throughout the rest of this year, including advancing AXS-02 into trials in additional pain indications. As a reminder, AXS-02 is an oral, non-opioid, targeted, potentially first-in-class therapeutic which we are developing for chronic pain.”

2015 and Recent Corporate Highlights

- 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 the treatment of treatment resistant depression (TRD).
- In November 2015, successfully completed an initial public offering (IPO) of common stock, which raised gross proceeds of approximately \$51 million.
- In October 2015, received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA) for the COAST-1 (Clinical Knee Osteoarthritis Symptom Treatment 1) study. COAST-1 is a Phase 3 clinical trial of AXS-02 for the treatment of the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs).
- In July 2015, enrolled the first patient in the CREATE-1 (CRPS Treatment Evaluation 1) study, a Phase 3 trial evaluating the efficacy and safety of AXS-02 for the treatment of complex regional pain syndrome (CRPS).
- Began preparations to file an Initial Drug Application (IND) for a Phase 3 trial of AXS-02 for the treatment of chronic low back pain (CLBP) associated with Modic changes (MCs). Initiation of this trial is currently anticipated in the fourth quarter of 2016 or the first quarter of 2017.

Fourth Quarter and Full Year 2015 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were \$2.2 million for the quarter ended December 31, 2015, and \$6.8 million for the year ended December 31, 2015, compared to \$1.3 million and \$4.3 million for the comparable periods in 2014. The increase in R&D expenses was primarily due to increased clinical trial expenses related to the initiation of the CREATE-1 study, increased manufacturing expenses for Axsome’s two lead product candidates, AXS-02 and AXS-05, and an increase in personnel costs and stock compensation expense in 2015. R&D expenses in 2016 are expected to increase as compared to 2015 in connection with the conduct of our Phase 3 clinical trials.
- **General and administrative (G&A) expenses:** G&A expenses were \$0.9 million for the quarter ended December 31, 2015, and \$2.4 million for the year ended December 31, 2015, compared to \$0.6 million and \$1.4 million for the comparable periods in 2014. The increase in G&A expenses was primarily due to an increase in personnel costs, stock compensation expense, and professional fees associated with becoming a public company. G&A expenses are expected to increase in 2016 as compared to 2015 primarily associated with the costs of being a public company.
- **Net loss:** Net loss was \$1.7 million, or \$0.12 per share for the quarter ended December 31, 2015, compared to a net

loss of \$1.5 million, or \$0.14 per share for the quarter ended December 31, 2014. Net loss for the year ended December 31, 2015 was \$10.6 million, or \$0.88 per share, compared to a net loss of \$6.0 million, or \$0.66 per share for the year ended December 31, 2014.

- **Cash:** As of December 31, 2015, Axsome had \$48.0 million of cash compared to \$2.6 million of cash as of December 31, 2014. The increase in cash is principally related to the company’s IPO, completed in November 2015, which raised gross proceeds of approximately \$51.0 million and net proceeds of approximately \$45.5 million, after deducting underwriting discounts and commissions and offering-related transaction costs. Axsome currently anticipates that its cash will be sufficient to fund its anticipated operations into the third quarter of 2017.
- **Shares outstanding:** At December 31, 2015, 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. Axsome’s product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in a Phase 3 trial in complex regional pain syndrome (CRPS), with additional Phase 3 trials planned in knee osteoarthritis (OA) associated with bone marrow lesions (BMLs), and chronic low back pain (CLBP) associated with Modic changes (MCs). AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD). AXS-02 and AXS-05 are investigational products 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:

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 2,207,915	\$ 1,347,527	\$ 6,776,987	\$ 4,279,200

General and administrative	946,618	600,837	2,419,289	1,392,830
Total operating expenses	3,154,533	1,948,364	9,196,276	5,672,030
Loss from operations	(3,154,533)	(1,948,364)	(9,196,276)	(5,672,030)
Interest and amortization of debt discount/premium income (expense)	1,534,597	334,198	914,952	2,233,338
Tax credit	—	—	—	184,139
Change in fair value of warrant liability	(93,976)	(57,106)	(108,539)	(57,106)
Change in fair value of embedded derivative liabilities	—	182,000	274,800	182,000
Loss on extinguishment of debt	—	—	(2,444,516)	(2,870,903)
Net loss	\$ (1,713,912)	\$ (1,489,272)	\$ (10,559,579)	\$ (6,000,562)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.14)	\$ (0.88)	\$ (0.66)
Weighted average common shares outstanding – basic and diluted	14,429,540	10,998,556	11,945,318	9,099,188

Balance Sheet Information:

	December 31, 2015	December 31, 2014
Cash	\$ 48,036,260	\$ 2,617,815
Total assets	49,076,156	2,786,380
Accumulated deficit	(18,788,798)	(8,229,219)
Stockholders' equity (deficit)	\$ 46,444,261	\$ (3,202,575)

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