Axsome Therapeutics Reports First Quarter 2017 Financial Results

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NEW YORK, May 09, 2017 (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, 2017.

“In the first quarter we continued to advance all of our clinical programs, which include three ongoing Phase 3 trials with our lead product candidates AXS-02 and AXS-05,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. “The recently completed common stock offering bolsters our balance sheet and provides the financial resources to maintain our pipeline momentum.”

Pipeline Update

Axsome is developing a portfolio of differentiated, patent-protected, CNS product candidates. CNS disorders are distressing, difficult-to-treat, and underserved with many having no approved or satisfactory treatments. Axsome accelerates the development of new CNS medicines in a cost-efficient manner, by utilizing novel mechanisms of action and novel delivery approaches of well-characterized molecules, combined with human proof-of-concept data and innovative clinical trial designs. Our pipeline includes two late-stage product candidates in Phase 3 development and preclinical candidates.

- **AXS-05:** Axsome is developing AXS-05 (bupropion and dextromethorphan fixed-dose combination) in two separate Phase 3 clinical programs for treatment resistant depression (TRD) and Alzheimer’s disease (AD) agitation.

  TRD: In February 2017, the U.S. Food and Drug Administration (FDA) granted Axsome Fast Track designation for AXS-05 for TRD. Axsome is enrolling the STRIDE-1 study, a Phase 3, multicenter, randomized, double-blind, active-controlled trial to assess the efficacy and safety of AXS-05 in TRD, defined as major depressive disorder which has failed to respond to two or more antidepressant treatments.

  AD Agitation: In May 2017, the FDA granted Axsome Fast Track designation for AXS-05 for the treatment of AD agitation. In January 2017, Axsome received Investigational New Drug Application (IND) clearance from the FDA to proceed with a Phase 2/3 trial of AXS-05 in this indication. Axsome anticipates commencing this trial in the second quarter of 2017.

- **AXS-02:** Axsome is developing AXS-02 (disodium zoledronate tetrahydrate) in three separate Phase 3 clinical programs: complex regional pain syndrome (CRPS), knee osteoarthritis (OA) associated with bone marrow lesions (BMLs), and chronic low back pain (CLBP) associated with Modic changes (MCs).

  CRPS: Axsome is enrolling the CREATE-1 study, a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial to assess the efficacy and safety of AXS-02 in the treatment of pain in patients with CRPS. CREATE-1 incorporates an interim analysis for efficacy which will be conducted on the first approximately 95 enrolled subjects.

  Knee OA associated with BMLs: Axsome is evaluating AXS-02 in the COAST-1 study, a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial to assess the efficacy and safety of AXS-02 in the treatment of the pain of knee OA associated with BMLs. Screening of subjects in this trial is paused pending results of the interim analysis on the first approximately 60 subjects enrolled in the trial to assess the assumptions used to determine the sample size of the study.

CLBP associated with MCs: In February 2017, Axsome received IND clearance from the FDA to proceed with a Phase 3 trial of AXS-02 in the treatment of CLBP associated with MCs. The start of this trial is planned following readouts from Axsome's ongoing Phase 3 trials in CRPS and TRD.

- **Other Programs:** Axsome is currently evaluating additional product candidates, including AXS-06, that it intends to develop for CNS disorders, including chronic pain.

Corporate Update

- In March 2017, Axsome completed an underwritten public offering of common stock raising gross proceeds of approximately $16.1 million, which includes full exercise of the underwriter's option to purchase additional shares.

Anticipated Near-Term Clinical Milestones

- **Clinical Trial Initiations:**

  -- Phase 2/3 clinical trial of AXS-05 in AD agitation (2Q 2017)

- **Clinical Trial Readouts:**

  -- Phase 3 COAST-1 trial of AXS-02 in knee OA associated with BMLs, interim analysis (3Q 2017)

  -- Phase 3 CREATE-1 trial of AXS-02 in CRPS, interim efficacy analysis (4Q 2017)

  -- Phase 3 STRIDE-1 trial of AXS-05 in TRD, top-line data (1Q 2018)

First Quarter 2017 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $6.0 million for the quarter ended March 31, 2017 compared to $4.5 million for the comparable period in 2016. The increase in R&D expenses was primarily due to the conduct of the CREATE-1, STRIDE-1, and COAST-1 Phase 3 clinical trials, as well as product candidate manufacturing costs.

- **General and administrative (G&A) expenses:** G&A expenses were $1.7 million for the quarter ended March 31, 2017 compared to $1.4 million for the comparable period in 2016. The increase in G&A expenses was primarily related to stock compensation expense.

- **Net loss:** Net loss was $8.0 million, or $(0.41) per share, for the quarter ended March 31, 2017 compared to a net loss of $5.9 million, or $(0.31) per share, for the quarter ended March 31, 2016.

- **Cash:** As of March 31, 2017, Axsome had $45.0 million of cash compared to $36.6 million of cash as of December 31, 2016.

- **Shares outstanding:** As of March 31, 2017, Axsome had 23,543,667 shares of common stock outstanding.

- **Financial guidance:** Axsome believes that its cash as of March 31, 2017 will be sufficient to fund the company's anticipated operations, based on its current operating plans, into the first quarter of 2019.

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 treatment options. Axsome's product candidate

portfolio includes two late-stage candidates, AXS-05 and AXS-02. 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 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 and AXS-02 are investigational drug 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, interim analyses 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,	
	2017	**2016**
Operating expenses:		
Research and development	$ 5,985,219	$ 4,526,252
General and administrative	1,686,814	1,356,613
Total operating expenses	7,672,033	5,882,865
Loss from operations	(7,672,033)	(5,882,865)
Interest and amortization of debt discount/premium (expense) income	(323,006)	16,924
Net loss	$ (7,995,039)	$ (5,865,941)
Net loss per common share – basic and diluted	$ (0.41)	$ (0.31)
Weighted average common shares outstanding – basic and diluted	19,537,897	19,149,417

Balance Sheet Information:

	March 31, 2017 (unaudited)	December 31, 2016*
Cash	$ 45,019,627	$ 36,618,497
Total assets	46,411,558	38,212,608
Loan payable, current and long-term	9,855,252	9,739,607
Accumulated deficit	(55,636,490)	(47,641,451)
Stockholders' equity	$ 29,280,480	$ 21,571,451

*Condensed from audited financial statements.

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