UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

May 8, 2017
Date of report (Date of earliest event reported)

Axsome Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37635**	**45-4241907**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

25 Broadway, 9th Floor **New York, New York**	**10004**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(212) 332-3241**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 2.02. Results of Operations and Financial Condition

On May 9, 2017, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2017 and an update on the Company's operations. The Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or

otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On May 8, 2017, the Company issued a press release announcing that it had received, from the U.S. Food and Drug Administration, Fast Track designation for one of the Company's lead product candidates, AXS-05, for the treatment of Alzheimer's disease agitation.

The full text of the press release is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 9, 2017.
99.2	Press release dated May 8, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Axsome Therapeutics, Inc.

Dated: May 9, 2017

By: /s/ Herriot Tabuteau, M.D.
Name: Herriot Tabuteau, M.D.
Title: Chief Executive Officer

AXSOME THERAPEUTICS

Axsome Therapeutics Reports First Quarter 2017 Financial Results

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.

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

AXSOME THERAPEUTICS

Axsome Therapeutics Receives FDA Fast Track Designation for AXS-05 for Alzheimer's Disease Agitation

NEW YORK, May 08, 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, received Fast Track designation from the U.S. Food and Drug Administration (FDA) for AXS-05 for the treatment of agitation in patients with Alzheimer's disease (AD). There are currently no approved treatments for this condition. Axsome previously received Investigational New Drug Application (IND) clearance from the FDA to proceed with a Phase 2/3 trial of AXS-05 in this indication.

"Agitation is reported in nearly half of individuals living with Alzheimer's disease, results in distress to patients and caregivers, and has significant consequences including early nursing home placement and increased mortality," said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. "The receipt of Fast Track designation from the FDA highlights the serious nature of this condition, the lack of FDA-approved treatments, and the potential of AXS-05 to address this high unmet medical need."

The FDA's Fast Track designation program is designed to aid in the development and expedite the review of drugs that are intended to treat serious or life-threatening conditions. In order to receive Fast Track designation, a product must also demonstrate the potential to address an unmet medical need. Fast Track designation provides greater access to, and more frequent communication with, the FDA throughout the entire drug development and review process, with the goal of getting important new drugs to patients more rapidly. It also provides the opportunity to submit sections of a New Drug Application (NDA) on a rolling basis, where the FDA may review portions of the NDA as they are received instead of waiting for the entire NDA submission. In addition, Fast Track designated products are eligible for Priority Review at the time of NDA submission.

About Alzheimer's Disease (AD) Agitation

Alzheimer's disease (AD) is a progressive neurodegenerative disorder that manifests initially as forgetfulness advancing to severe cognitive impairment and memory loss. It afflicts an estimated 5 million individuals in the United States, a number that is anticipated to increase to approximately 14 million by 2050. In addition to cognitive decline, individuals diagnosed with AD typically experience behavioral and psychological symptoms including agitation which is reported in approximately 45% of patients. Agitation is characterized by emotional distress, aggressive behaviors, disruptive irritability, and disinhibition. Agitation in patients with AD has been associated with increased caregiver burden, decreased functioning, earlier nursing home placement, and increased mortality. There are currently no therapies approved by the FDA for the treatment of agitation in patients with AD.

About AXS-05

AXS-05 is a novel, oral, investigational drug product under development for the treatment of central nervous system (CNS) disorders. AXS-05 utilizes Axsome's technology of combining bupropion and dextromethorphan. Dextromethorphan is an NMDA receptor antagonist, sigma-1 receptor agonist, and inhibitor of the serotonin and norepinephrine transporters. Bupropion serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor, and a nicotinic acetylcholine receptor antagonist. AXS-05 is an investigational drug product not approved by the FDA.

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 completion, timing and proceeds of the public offering; 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 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