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

March 24, 2016
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:

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

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

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

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

Item 2.02. Results of Operations and Financial Condition

On March 24, 2016, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months and fiscal year ended December 31, 2015 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 March 28, 2016, the Company issued a press release announcing that it had enrolled the first patient in the Company's Phase 3 COAST-1 (Clinical Knee Osteoarthritis Symptom Treatment 1) clinical trial evaluating the efficacy and safety of one of the Company's lead product candidates, AXS-02, for the treatment of the pain of knee osteoarthritis associated with bone marrow lesions.

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 March 24, 2016.
99.2	Press release dated March 28, 2016.

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: March 29, 2016

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

Exhibit 99.1

AXSOME THERAPEUTICS

Axsome Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results

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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AXSOME THERAPEUTICS

Axsome Therapeutics Initiates Phase 3 Study of AXS-02 for Knee Osteoarthritis Associated with Bone Marrow Lesions

First Patient Enrolled in the COAST-1 Study
Non-Opioid, Oral, Targeted, Potentially First-in-Class Mechanism for Pain
Novel Biomarker-Based Approach for the Treatment of Knee Osteoarthritis Pain
COAST-1 Study Being Conducted under FDA Special Protocol Assessment

NEW YORK, March 28, 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, 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 treatment of the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs). AXS-02 is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain.

"BMLs, which are visible on MRI, are linked to knee pain and cartilage damage, and are present in a significant percentage of patients with knee OA," said Graeme Jones, M.D., Professor of Rheumatology and Epidemiology and Head of the Musculoskeletal Unit at the Menzies Research Institute (University of Tasmania), and Head of the Department of Rheumatology at Royal Hobart Hospital. "Unfortunately there is currently no drug approved to treat knee OA pain associated with BMLs. This trial is important because it explores a potential treatment for this unmet need, and because it is the first knee OA trial for regulatory approval to use BMLs for patient selection."

The COAST-1 study is being conducted pursuant to a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). An SPA documents the FDA's agreement that the design and planned analysis of a clinical trial adequately address scientific and regulatory objectives that, if met, would support a regulatory submission for approval of a drug.

"Knee OA is a significant source of chronic disability for millions of patients. A hallmark of the condition is joint pain, often associated with bone changes, including osteophytes and BMLs. These processes can lead to loss of normal joint function and may progress to eventual joint failure resulting from progressive cartilage loss," said Thomas J. Schnitzer, M.D., Ph.D., Professor in the Departments of Physical Medicine and Rehabilitation, and Internal Medicine-Rheumatology, at Northwestern University Feinberg School of Medicine. "The condition substantially decreases day-to-day functioning and quality of life, and may necessitate surgical replacement of the knee joint."

"We believe that AXS-02 holds promise in the treatment of knee OA due to its unique, non-opioid mechanisms of action for pain," said Randall Kaye, M.D., Chief Medical Officer of Axsome. "AXS-02 potently inhibits bone turnover and localizes preferentially to regions of increased turnover. BMLs therefore represent an entirely novel biomarker strategy for identifying knee OA patients that may respond to AXS-02 treatment."

"We are pleased to initiate a Phase 3 trial in this important indication which touches the lives of so many," said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. "The initiation of the COAST-1 study represents the achievement of another key milestone for Axsome, following our initial public offering in November 2015. Axsome has now initiated three pivotal trials, in three indications, with two product candidates, in less than one year."

About the COAST-1 Study

COAST-1 (Clinical Knee Osteoarthritis Symptom Treatment 1) is a randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of AXS-02 administered orally to patients with knee osteoarthritis (OA) associated with bone marrow lesions (BMLs). This trial is anticipated to enroll approximately 346 patients with clinically diagnosed knee OA and at least one confirmed BML in the affected knee on MRI. Eligible patients must be at least 50 years of age, either male or postmenopausal female, and have at least moderate pain intensity. After a baseline period, patients meeting the entry criteria will be randomized in a 1:1 ratio to receive either (1) AXS-02 tablets once per week or (2) matching placebo tablets once per week, under fasting conditions for 6 weeks. Randomized patients will remain blinded for an additional 18 weeks, totaling 24 weeks for the double-blind

phase. The primary endpoint is the change in pain intensity from baseline to week 24, measured using a 0-10 numerical rating scale (NRS). Axsome has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) for the COAST-1 study. The SPA provides agreement that the design and planned analysis of the COAST-1 study adequately address objectives that, if met, would support a regulatory submission for approval of AXS-02 for the treatment of the pain of knee OA associated with BMLs.

About AXS-02

AXS-02 (disodium zoledronate tetrahydrate) is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain. AXS-02 has a high affinity for bone mineral, and reduces osteoclast activity by inhibiting the farnesyl pyrophosphate synthase (FPPS) enzyme. AXS-02 is being developed for the treatment of complex regional pain syndrome (CRPS), the pain of knee osteoarthritis (OA) associated with bone marrow lesions (BMLs), and chronic low back pain (CLBP). Phase 3 trials are underway with AXS-02 in CRPS and knee OA associated with BMLs, and are planned in CLBP. AXS-02 is an investigational medication not approved by the FDA.

About Knee Osteoarthritis (OA) associated with Bone Marrow Lesions (BMLs)

Knee OA is a disorder characterized by periarticular bone changes, progressive loss of articular cartilage, joint space narrowing, and eventual total joint failure. It is clinically manifested by knee pain, significant physical disability, and reduced quality of life. BMLs are regions of increased signal intensity on magnetic resonance imaging (MRI) of the knee in patients with knee OA. BMLs are strongly associated with the presence and severity of knee pain, and predict disease severity and structural progression in patients with knee OA, based on published studies. Results of epidemiological studies suggest that there are approximately 7 million symptomatic patients in the United States, 50 years of age and older, with radiographic knee OA and BMLs.

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