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

April 23, 2018
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 8.01. Other Events.

On April 23, 2017, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing the enrollment of the first patient into a Phase 2 trial of AXS-05 for smoking cessation treatment, which is being conducted under a research collaboration between Duke University and Axsome Therapeutics.

The full text of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated April 23, 2018.

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: April 23, 2018

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

AXSOME THERAPEUTICS

Axsome Therapeutics Announces First Patient Enrolled in Phase 2 Clinical Trial of AXS-05 in Smoking Cessation

Trial being conducted in collaboration with Duke University

NEW YORK, April 23, 2018 (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 announced the enrollment of the first patient into a Phase 2 trial of AXS-05 for smoking cessation treatment. The trial is being conducted under a research collaboration between Duke University and Axsome Therapeutics. Duke University is recognized as one of the world's leading centers for smoking cessation research.

AXS-05 is a novel, oral, fixed-dose combination of dextromethorphan and bupropion, and utilizes Axsome's metabolic inhibition technology. Both components of AXS-05 are nicotinic acetylcholine receptor antagonists. The scientific rationale for the study of AXS-05 in smoking cessation is further based on animal research conducted at Duke University demonstrating the ability of the dextromethorphan component of AXS-05 to reduce nicotine self-administration, human studies conducted by Axsome demonstrating increased dextromethorphan plasma concentrations with AXS-05, and the established efficacy in human studies of the bupropion component of AXS-05 in smoking cessation.

The trial is a Phase 2, randomized, double-blind, active-controlled study to evaluate the efficacy and safety of AXS-05 for smoking cessation treatment. Approximately 60 smokers interested in quitting will be randomized in a 1:1 ratio to receive either AXS-05 or bupropion for 4 weeks. The primary outcome measure is the change in smoking intensity. Smoking intensity will be measured using the number of cigarettes smoked per day, salivary cotinine, and carbon monoxide breath testing. Secondary outcome measures include smoking abstinence, measured using a 7-day abstinence test, adherence to treatment, withdrawal symptoms, stress, anxiety, and depression. The trial is being conducted at the Duke Center for Smoking Cessation. Additional information on the trial can be found at ClinicalTrials.gov (study identifier NCT03471767).

Smoking cessation is the third indication for AXS-05, which is also being developed in late-stage clinical trials for treatment resistant depression and agitation in patients with Alzheimer's disease.

About Smoking

Nearly 40 million American adults smoke and around 70% report that they want to quit. Tobacco use results in approximately 500,000 premature deaths each year in the U.S., according to the Centers for Disease Control and Prevention. Smoking is the single largest cause of premature deaths worldwide accounting for an estimated almost 20% of all deaths in developed countries [1]. Direct health care and lost productivity costs as a result of smoking total nearly $300 billion a year in the U.S. alone. It is estimated that only 3 to 5% of cigarette smokers who attempt to quit without assistance are successful for 6 to 12 months, and that relapse rates remain above 80% even with current treatments [2].

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 consists of bupropion and dextromethorphan and utilizes Axsome's metabolic inhibition technology. Dextromethorphan is an NMDA receptor antagonist, sigma-1 receptor agonist, nicotinic acetylcholine receptor antagonist, 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 five clinical-stage candidates, AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD), and a Phase 2 trial in smoking cessation. AXS-02 is currently in a Phase 3 trial in 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-07 is being developed for the acute treatment of migraine. AXS-06 is being developed for the treatment of osteoarthritis and rheumatoid arthritis and for the reduction of the risk of NSAID-associated gastric ulcers. AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09 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". The Company 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 the Company's ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation, interim analyses and completion of the trials; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its 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.

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[1] Dani JA, Heinemann S. Molecular and cellular aspects of nicotine abuse. Neuron. 1996 May;16(5):905-8.

[2] Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence among untreated smokers. Addiction. 2004 Jan;99(1):29-38.