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

August 10, 2020
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.)

22 Cortlandt Street, 16th Floor **New York, New York** (Address of principal executive offices)	**10007** (Zip Code)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock, Par Value $0.0001 Per Share	AXSM	The Nasdaq Global Market

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))

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 ☒

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. ☒

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2020, Axsome Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three months ended June 30, 2020 and provided 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 August 10, 2020, the Company issued a press release providing an update on the progress of its AXS-05 clinical product candidate.

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 No.	Description
99.1	Press Release dated August 10, 2020.
99.2	Press Release dated August 10, 2020.

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: August 10, 2020

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

AXSOME THERAPEUTICS

Axsome Therapeutics Reports Second Quarter 2020 Financial Results and Provides Business Update

Two NDA submissions, for AXS-05 in MDD and for AXS-07 in migraine, on track for 4Q 2020

Enrollment completed for both the AXS-05 Phase 3 long-term safety trial in MDD, and for the AXS-07 Phase 3 long-term safety trial in migraine

Results from three Phase 2 open-label efficacy trials of AXS-05 in TRD, antidepressant unresponsive MDD, and suicidal ideation, expected in 4Q 2020

Phase 3 trials for AXS-05 in Alzheimer's disease agitation and for AXS-12 in narcolepsy on track for 4Q 2020

Three FDA Breakthrough Therapy designations, in MDD, Alzheimer's disease agitation, and narcolepsy, highlight Axsome's broad, differentiated, late-stage CNS pipeline

Company to host conference call today at 8:00 AM Eastern

NEW YORK, August 10, 2020 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today reported financial results for the second quarter ended June 30, 2020.

"Axsome is committed to developing potentially life-changing medicines for patients living with difficult-to-treat CNS disorders. Over the past several months, we achieved a number of significant clinical and regulatory milestones including receipt of Breakthrough Therapy designations from the FDA for AXS-05 for the treatment of Alzheimer's disease agitation, and for AXS-12 for the treatment of cataplexy in patients with narcolepsy. Our industry-leading, late-stage CNS pipeline has now been granted three FDA Breakthrough Therapy designations, highlighting the potential for significant advances in patient care," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We remain on track to submit two New Drug Applications to the FDA, for AXS-05 in depression and for AXS-07 in migraine, by year-end. We expect to launch the second pivotal trial of AXS-05 in Alzheimer's disease agitation as well as pivotal trials of AXS-12 in narcolepsy by year end. We also unveiled three new Phase 2 open-label efficacy trials of AXS-05 in three different clinically pertinent depressed populations. These trials are designed to further characterize the novel antidepressant profile of AXS-05 across a broad spectrum of patients with major depressive disorder, with results expected in the fourth quarter. Having achieved a number of key milestones and with more on the horizon, our team is expanding to support launch-readiness efforts and our growing pipeline."

CNS Pipeline Update

Axsome is developing a portfolio of differentiated, patent-protected, central nervous system (CNS) product candidates. For the many people living with serious CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. The Company's CNS pipeline includes four differentiated product candidates in active clinical development.

- **AXS-05:** AXS-05 (dextromethorphan/bupropion modulated delivery tablet) is Axsome's novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for the following indications: major depressive disorder (MDD), Alzheimer's disease (AD) agitation, and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designations for MDD, and for AD agitation; as well as Fast Track designations for treatment resistant MDD (TRD), and for AD agitation.

  Depression: Axsome remains on track to submit a New Drug Application (NDA) to the FDA for AXS-05 for the treatment of MDD in the fourth quarter of 2020. In July 2020, Axsome announced it had completed a pre-NDA meeting for AXS-05 in MDD with the FDA to reach agreement on the proposed content and format of the Company's planned NDA submission, including the clinical and nonclinical requirements. Based on the feedback from the FDA, the Company believes its regulatory data package will be sufficient to support an NDA for AXS-05 in MDD. The NDA is supported by positive efficacy results from the ASCEND and GEMINI trials.

Enrollment has been completed in the COMET (Clinical Outcomes with NMDA-based Depression Treatment) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-05 in MDD. Nearly 900 patients have been enrolled, more than 500 of whom have been treated with AXS-05 for at least 6 months to date. At least 300 patients treated for 6 months and 100 patients treated for one year are required for the NDA filing. Axsome remains on track to achieve the required number of patients treated for one year in the fourth quarter.

Axsome is conducting three Phase 2 open-label efficacy sub-studies of the COMET trial which will evaluate the efficacy and safety of AXS-05 in three clinically pertinent MDD patient populations: the COMET-TRD trial in treatment resistant MDD (TRD), the COMET-AU trial in antidepressant unresponsive MDD, and the COMET-SI trial in MDD with suicidal ideation. Efficacy results from these studies are expected in the fourth quarter of 2020.

Axsome has initiated the MERIT (Mechanistic Evaluation of Response in TRD) trial, a Phase 2, double-blind, placebo-controlled, randomized withdrawal study in patients with TRD. Results from the MERIT trial are expected in the first half of 2021. The MERIT and COMET-TRD trials are being conducted in lieu of the previously planned Phase 3 trial in TRD. This approach will more quickly generate clinically useful information with AXS-05 in this treatment resistant MDD population, starting as early as the fourth quarter of 2020.

AD Agitation: In June 2020, Axsome received FDA Breakthrough Therapy designation for AXS-05 for the treatment of AD agitation. The designation was supported by the positive results from the pivotal ADVANCE-1 study, a randomized, double-blind, controlled, multicenter U.S. trial in which 366 Alzheimer's disease patients were treated with AXS-05, bupropion, or placebo. Axsome remains on track to initiate a second Phase 3 trial of AXS-05 in AD agitation in the second half of 2020.

Smoking Cessation: Axsome plans to meet with the FDA in the second half of 2020 to discuss the continued clinical development of AXS-05 as an aid to smoking cessation treatment. Axsome previously announced positive results from a Phase 2 trial of AXS-05 for smoking cessation treatment conducted under a research collaboration between Axsome and Duke University.

- **AXS-07:** AXS-07 (MoSEIC™ meloxicam/rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for the acute treatment of migraine.

  Migraine: Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials.

  Enrollment has been completed in the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-07 in the acute treatment of migraine. More than 700 patients have been enrolled, approximately 450 of whom have been treated with AXS-07 for at least 6 months to date. At least 300 patients treated for 6 months and 100 patients treated for one year are required for the NDA filing. Axsome remains on track to achieve the required number of patients treated for one year in the third quarter.

- **AXS-12:** AXS-12 (reboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the treatment of narcolepsy. AXS-12 has been granted FDA Breakthrough Therapy designation for the treatment of cataplexy in patients with narcolepsy and Orphan Drug Designation for the treatment of narcolepsy.

  Narcolepsy: In August 2020, Axsome received FDA Breakthrough Therapy designation for AXS-12 for the treatment of cataplexy in patients with narcolepsy. The designation was supported by the positive results from the Phase 2 CONCERT study, a randomized, double-blind, placebo-controlled, crossover, multicenter U.S. trial in which 21 patients with a diagnosis of narcolepsy with cataplexy were treated with AXS-12 or with placebo, followed by a crossover to the other treatment. Axsome is on track to initiate Phase 3 trials of AXS-12 in the treatment of narcolepsy in the second half of 2020.

- **AXS-14:** AXS-14 (esreboxetine) is Axsome's novel, oral, potent, and highly selective norepinephrine reuptake inhibitor for the treatment of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine.

  Fibromyalgia: Axsome plans to meet with the FDA in the second half of 2020 to discuss the further clinical development of AXS-14 for the treatment of fibromyalgia. AXS-14 has previously met the primary endpoints and demonstrated positive and statistically significant results in a Phase 3 and a Phase 2 trial in the treatment of fibromyalgia.

Anticipated Milestones

- **NDA Filings:**
    - AXS-05 in the treatment of MDD (4Q 2020)
    - AXS-07 in the acute treatment of migraine (4Q 2020)
- **FDA Meetings:**
    - AXS-05 for AD agitation (2H 2020)
    - AXS-05 for smoking cessation (2H 2020)
    - AXS-12 for narcolepsy (2H 2020)
    - AXS-14 for fibromyalgia (2H 2020)
- **Clinical Trial Readouts:**
    - Phase 2 COMET-TRD trial of AXS-05 in TRD, topline data (4Q 2020)
    - Phase 2 COMET-AU trial of AXS-05 in antidepressant unresponsive MDD, topline data (4Q 2020)
    - Phase 2 COMET-SI trial of AXS-05 in MDD with suicidal ideation, topline data (4Q 2020)
    - Phase 2 MERIT trial of AXS-05 in TRD, topline data (1H 2021)
- **Clinical Trial Initiations:**
    - Phase 3 trials of AXS-12 in narcolepsy (2H 2020)
    - Phase 3 trial of AXS-05 in AD agitation (2H 2020)

Second Quarter 2020 Financial Results

- **Research and development (R&D) expenses:** R&D expenses were $10.5 million for the quarter ended June 30, 2020 and $11.0 million for the comparable period in 2019. The decrease of $0.5 million was driven by the completion of several clinical trials which were ongoing in the comparable prior period.
- **General and administrative (G&A) expenses:** G&A expenses were $7.2 million for the quarter ended June 30, 2020 and $2.4 million for the comparable period in 2019. The change was primarily due to an increase in stock compensation expense, along with the build-out of the commercial function.
- **Net loss:** Net loss was $18.3 million, or $(0.49) per share for the quarter ended June 30, 2020, compared to a net loss of $13.8 million, or $(0.41) per share for the comparable period in 2019.
- **Cash:** At June 30, 2020, Axsome had $190.7 million of cash compared to $197.3 million of cash at March 31, 2020.
- **Shares outstanding:** At June 30, 2020, Axsome had 37,267,510 shares of common stock outstanding.
- **Financial Guidance:** Axsome believes that its cash at June 30, 2020 will be sufficient to fund the Company's anticipated operations, based on its current operating plans, for at least two years.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss second quarter 2020 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (844) 698-4029 (toll-free domestic) or (647) 253-8660 (international), and use the conference ID 4876676. The live webcast can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the webcast will be available for approximately 30 days following the live event.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. For the many people facing unsatisfactory treatments for CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. Axsome's core CNS product candidate portfolio includes five clinical-stage candidates, AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14. AXS-05 is being developed for major depressive disorder (MDD), treatment resistant depression (TRD), Alzheimer's disease (AD) agitation, and as treatment for smoking cessation. AXS-07 is being developed for the acute treatment of migraine. AXS-12 is being developed for the treatment of narcolepsy. AXS-14 is being developed for fibromyalgia. AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14 are investigational drug products not approved by the FDA. For more information, please visit the Company's website at 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, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application ("NDA") for any of our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA's agreement with the Company's discontinuation of the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the MOMENTUM clinical trial to provide a basis for approval of AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment; the potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; 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; the Company's anticipated capital requirements, including the Company's anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; 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 June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 10,542,957	$ 11,003,142
General and administrative	7,235,877	2,445,077
Total operating expenses	17,778,834	13,448,219
Loss from operations	(17,778,834)	(13,448,219)
Interest income (expense)	(548,158)	(313,995)
Net loss	$ (18,326,992)	$ (13,762,214)
Net loss per common share, basic and diluted	$ (0.49)	$ (0.41)
Weighted average common shares outstanding, basic and diluted	37,100,770	33,801,749

Balance Sheet Information:

	June 30, 2020	**December 31, 2019**
Cash and cash equivalents	$ 190,682,109	$ 219,966,167
Total assets	190,989,587	220,549,760
Loan payable, current and long-term	20,291,582	19,934,918
Accumulated deficit	(226,706,631)	(175,895,493)
Stockholders' equity	$ 154,243,310	$ 178,722,389

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AXSOME THERAPEUTICS

Axsome Therapeutics Announces Further Progress in AXS-05 Depression Clinical Program

Enrollment complete in the COMET Phase 3 long-term safety trial of AXS-05 in MDD; NDA filing on track for 4Q 2020

Results from three Phase 2 open-label efficacy trials of AXS-05 in TRD, antidepressant unresponsive MDD, and suicidal ideation, expected in 4Q 2020

MERIT Phase 2 placebo-controlled trial in TRD initiated; topline results expected in 1H 2021

NEW YORK, August 10, 2020 (Globe Newswire) – Axsome Therapeutics, Inc. (NASDAQ: AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, announces continued progress toward NDA filing of AXS-05 in the treatment of major depressive disorder (MDD), and the generation of new clinical data to further characterize the antidepressant profile of AXS-05 across a broad spectrum of patients with MDD.

Enrollment has been completed in the COMET (Clinical Outcomes with NMDA-based Depression Treatment) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-05 in MDD. In addition, the required number of patients treated for 6 months has been reached. Filing of the NDA remains on track for the fourth quarter of 2020.

Axsome is also conducting three Phase 2 open-label efficacy sub-studies of the COMET trial which will evaluate the efficacy and safety of AXS-05 in three clinically pertinent MDD patient populations: the COMET-TRD trial in treatment resistant MDD (TRD), the COMET-AU trial in antidepressant unresponsive MDD, and the COMET-SI trial in MDD with suicidal ideation. Efficacy results from these studies are expected in the fourth quarter of 2020.

Further, Axsome has initiated the MERIT (Mechanistic Evaluation of Response in TRD) trial, a Phase 2, double-blind, placebo-controlled, randomized withdrawal study in patients with TRD. Results from the MERIT trial, which are expected in the first half of 2021, along with results from the COMET-TRD trial, which are expected in the fourth quarter of 2020, will provide clinically useful information with AXS-05 in this treatment resistant MDD population.

Depression Clinical Program Update

Major Depressive Disorder (MDD) NDA

- Enrollment has been completed in the COMET Phase 3, open-label, long-term safety trial of AXS-05 to support the New Drug Application (NDA) filing in MDD. Nearly 900 patients have been enrolled, of whom more than 500 have been treated for at least 6 months to date. At least 300 patients treated for 6 months and 100 patients treated for one year are required for the NDA filing. Axsome remains on track to achieve the required number of patients treated for one year in the fourth quarter.

- Axsome previously announced that it had completed a pre-NDA meeting for AXS-05 in MDD with the U.S. Food and Drug Administration (FDA) to reach agreement on the proposed content and format of the Company's planned NDA submission, including the clinical and nonclinical requirements. Based on the feedback from the FDA, the Company believes its regulatory data package will be sufficient to support an NDA for AXS-05 in MDD, and Axsome remains on track to submit the planned NDA in the fourth quarter of 2020.

Treatment Resistant MDD (TRD)

- COMET-TRD Trial – Axsome is conducting the COMET-TRD trial, a Phase 2 open-label sub-study evaluating the efficacy and safety of AXS-05 in TRD patients. The trial will include approximately 70 patients who have had ongoing symptoms of depression despite receiving treatment with two or more prior antidepressants during the current major depressive episode. The trial endpoints will include the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score, clinical response, and remission. Topline results from the COMET-TRD trial are expected in the fourth quarter of 2020.

- MERIT Trial – Axsome is conducting the MERIT trial, a Phase 2, double-blind, placebo-controlled, randomized withdrawal study of AXS-05 in patients with TRD. The trial will include approximately 50 patients who have had ongoing symptoms of depression despite receiving treatment with two or more prior antidepressants during the current major depressive episode. In this trial, patients who experience a sustained remission of depressive symptoms after treatment with open-label AXS-05 will be randomized to continued treatment with AXS-05 or to placebo in a double-blind fashion. The primary endpoint of the trial is the time to relapse of depressive symptoms. Topline results from the MERIT trial are expected in the first half of 2021.

- The MERIT and COMET-TRD trials are being conducted in lieu of the previously planned Phase 3 trial in TRD. This approach will more quickly generate clinically useful information with AXS-05 in this treatment resistant MDD population, starting as early as the fourth quarter of 2020.

Antidepressant Unresponsive MDD

- COMET-AU Trial – Axsome is conducting the COMET-AU trial, a Phase 2 open-label sub-study evaluating the efficacy and safety of AXS-05 in patients with antidepressant unresponsive (AU) MDD. The trial will include approximately 150 patients with ongoing symptoms of depression despite receiving one standard antidepressant pharmacotherapy. The trial endpoints will include the change from baseline in the MADRS total score, clinical response, and remission. Topline results from the COMET-AU trial are expected in the fourth quarter of 2020.

MDD with Suicidal Ideation

- COMET-SI Trial – Axsome is conducting the COMET-SI trial, a Phase 2 open-label sub-study evaluating the efficacy and safety of AXS-05 in MDD patients with suicidal ideation (SI). The trial will include approximately 30 patients. The trial endpoints will include the resolution of suicidal ideation. Topline results from the COMET-SI trial are expected in the fourth quarter of 2020.

About Major Depressive Disorder (MDD)

Major depressive disorder (MDD) is a debilitating, chronic, biologically-based disorder characterized by low mood, inability to feel pleasure, feelings of guilt and worthlessness, low energy, and other emotional and physical symptoms, and which impairs social, occupational, educational, or other important functioning. In severe cases, MDD can result in suicide. According to the National Institutes of Health, an estimated 7.1% of U.S. adults, or approximately 17 million, experience MDD each year[1]. According to the World Health Organization (WHO), depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease[2]. Nearly two thirds of diagnosed and treated patients do not experience adequate treatment response with currently available first-line therapy[3], highlighting the need for additional therapies with new mechanisms of action. The majority of initial failures also fail second-line treatment. Patients diagnosed with MDD are defined as having treatment resistant depression (TRD) if they have failed to respond to two or more antidepressant therapies.

About AXS-05

AXS-05 is a novel, oral, patent-protected, investigational NMDA receptor antagonist with multimodal activity under development for the treatment of major depressive disorder, Alzheimer's disease agitation, and other central nervous system (CNS) disorders. AXS-05 consists of a proprietary formulation and dose of dextromethorphan and bupropion and utilizes Axsome's metabolic inhibition technology. The dextromethorphan component of AXS-05 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist, also known as a glutamate receptor modulator, a sigma-1 receptor agonist, an inhibitor of the serotonin and norepinephrine transporters, a nicotinic acetylcholine receptor antagonist, and an inhibitor of microglial activation. The bupropion component of AXS-05 serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor, and a nicotinic acetylcholine receptor antagonist. AXS-05 is covered by more than 42 issued U.S. and international patents which provide protection out to 2034. AXS-05 has been granted U.S. Food and Drug Administration Breakthrough Therapy designation for major depressive disorder, Fast Track designation for treatment resistant depression, and Breakthrough Therapy and Fast Track designations for Alzheimer's disease agitation. AXS-05 is not approved by the FDA.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. For the many people facing unsatisfactory treatments for CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. Axsome's core CNS product candidate portfolio includes five clinical-stage candidates, AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14. AXS-05 is being developed for major depressive disorder (MDD), treatment resistant depression (TRD), Alzheimer's disease (AD) agitation, and as treatment for smoking cessation. AXS-07 is being developed for the acute treatment of migraine. AXS-12 is being developed for the treatment of narcolepsy. AXS-14 is being developed for fibromyalgia. AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14 are investigational drug products not approved by the FDA. For more information, please visit the Company's website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

References

1. National Institute of Mental Health. (2017). Major Depression. Retrieved from https://www.nimh.nih.gov/health/statistics/major-depression.shtml.

2. World Health Organization. Fact Sheets: Depression, accessed October 9, 2018, http://www.who.int/en/news-room/fact-sheets/detail/depression.

3. Rush AJ, et al. (2007) Am J. Psychiatry 163:11, pp. 1905-1917 (STAR*D Study).

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, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application (“NDA”) for any of our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA’s agreement with the Company’s discontinuation of the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee’s recommendations); the potential for the MOMENTUM clinical trial to provide a basis for approval of AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment; the potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; 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; the Company’s anticipated capital requirements, including the Company’s anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; 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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