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 6, 2019
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.)

200 Broadway, 3rd Floor **New York, New York**	**10038**
(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)

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:

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

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

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

oPre-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 May 6, 2019, Axsome Therapeutics, Inc. (the "Company") issued a press release (the "First Release") announcing that the development status and plan for AXS-05 in the treatment of major depressive disorder and treatment resistant depression have been expedited following a Breakthrough Therapy meeting with the U.S. Food and Drug Administration ("FDA"). A copy of the First Release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Additionally, on May 6, 2019, the Company issued a press release (the "Second Release") announcing the acceleration of the timeline for reporting topline results from the MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 trial of AXS-07 (MoSEIC™ meloxicam and rizatriptan) in the acute treatment of migraine, which is being conducted pursuant to an FDA Special Protocol Assessment ("SPA"). The full text of the Second Release is filed as Exhibit 99.2 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	First Release.
99.2	Second Release.

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 6, 2019

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

Axsome Therapeutics Announces Expedited Development and Pivotal Status for AXS-05 in the Treatment of Major Depressive Disorder based on FDA Breakthrough Therapy Meeting

Previously completed active-controlled ASCEND trial in MDD now considered as pivotal; sufficient with ongoing STRIDE-1 Phase 3 trial for NDA in MDD

Target randomization for STRIDE-1 Phase 3 trial reached; screening to continue to build required NDA safety database

Initiation of placebo-controlled Phase 3 trial in MDD anticipated in 2Q 2019; provides additional NDA path with ASCEND trial and builds required NDA safety database

Topline results of both STRIDE-1 Phase 3 trial in TRD and planned placebo-controlled Phase 3 trial in MDD expected in 2H 2019

AXS-05 has potential to be first oral NMDA receptor antagonist with multimodal activity for the treatment of depression

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

NEW YORK, May 6, 2019 (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 that the development status and plan for AXS-05 in the treatment of major depressive disorder (MDD) and treatment resistant depression (TRD) have been expedited following a Breakthrough Therapy meeting with the U.S. Food and Drug Administration (FDA). AXS-05 is a novel, oral, investigational NMDA receptor antagonist with multimodal activity.

As part of the expedited development program, the Company's previously completed ASCEND trial in MDD is now considered sufficient with the ongoing STRIDE-1 Phase 3 trial in TRD, if positive, to support the filing of an NDA (New Drug Application) for approval of AXS-05 for the treatment of MDD. Alternatively, Axsome may file an NDA for AXS-05 for the treatment of MDD with the completed ASCEND trial and a placebo-controlled Phase 3 trial of AXS-05 in MDD. Axsome intends to initiate this placebo-controlled Phase 3 MDD trial in the second quarter of 2019.

Target enrollment in the ongoing STRIDE-1 Phase 3 trial has been reached. Based on the now accelerated timeline to NDA filing, patient screening in this trial however will continue in order to build the agreed-upon patient safety database required for an NDA filing. Axsome now expects topline results for both the Phase 3 STRIDE-1 trial in TRD, and the planned placebo-controlled Phase 3 trial in MDD, in the second half of 2019, with an NDA filing anticipated in 2020.

Also, as part of the expedited development program, a TRD indication for AXS-05 can now be supported by a placebo-controlled Phase 3 trial in TRD, in conjunction with the ongoing STRIDE-1 active-controlled trial, if positive, and the completed ASCEND trial.

"Axsome is very pleased with the FDA feedback from our recent Breakthrough Therapy meeting, which provided defined, streamlined NDA paths for AXS-05 in both major depressive disorder and treatment resistant depression," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "The expedited development plan significantly accelerates the potential filing of an NDA, now expected in 2020, for approval of our novel, oral, NMDA receptor antagonist with multimodal activity for the treatment of depression. If successfully developed, AXS-05 would represent a novel antidepressant with one of the first new mechanisms of action in several decades for the treatment of patients with this debilitating condition."

Breakthrough Therapy Meeting Outcomes:

- Completed ASCEND trial in MDD, now considered as pivotal, is sufficient with the ongoing STRIDE-1 trial in TRD, if positive, to support an NDA filing for AXS-05 for the treatment of MDD.

- A placebo-controlled Phase 3 trial in MDD, if positive, in conjunction with the completed ASCEND trial may also support an NDA filing for AXS-05 in the treatment of MDD.

- A safety database of MDD and TRD patients totaling at least 300 patients treated with AXS-05 for at least six months and at least 100 patients treated for one year is required for the NDA filing. Patients completing the ongoing STRIDE-1 and the planned placebo-controlled Phase 3 MDD trials will enter an open-label safety extension trial to build the required safety database.

- A TRD indication may be supported by a placebo-controlled Phase 3 trial in TRD, if positive, in conjunction with the ongoing STRIDE-1 trial, if positive, and the completed ASCEND trial.

In March 2019, Axsome received Breakthrough Therapy Designation from the FDA for AXS-05 for the treatment of MDD. A Breakthrough Therapy designation is granted to potentially expedite development and review timelines for a promising investigational medicine when preliminary clinical evidence indicates it may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies for a serious or life-threatening condition. The designation for AXS-05 in MDD was supported by the recent positive results from the Phase 2 ASCEND study, a randomized, double-blind, active-controlled, multicenter, U.S. trial, in which 80 patients with confirmed moderate to severe MDD were treated with AXS-05 or the active comparator bupropion. In this trial, treatment with AXS-05 resulted in a substantial, rapid, and statistically significant reduction in depressive symptoms as compared to the active comparator bupropion. On the pre-specified primary endpoint, AXS-05 demonstrated a statistically significant average mean reduction from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score over the 6-week treatment period of 13.7 points for AXS-05 compared to 8.8 for bupropion ($p<0.001$). AXS-05 was safe and well tolerated with the most commonly reported adverse events in the AXS-05 arm being nausea, dizziness, dry mouth, decreased appetite, and anxiety.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss the expedited development plan for AXS-05 in the treatment of major depressive disorder following a Breakthrough Therapy meeting with the FDA. 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 3977129. 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 FDA Breakthrough Therapy Designation

Breakthrough Therapy designation is granted by the FDA in order to expedite the development and review of drugs for serious or life-threatening conditions. In order to receive Breakthrough Therapy designation, a drug must demonstrate preliminary clinical evidence that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. Breakthrough Therapy designation provides an organizational commitment involving senior managers from the FDA, more intensive FDA guidance on an efficient drug development program, and greater access to and more frequent communication with the FDA throughout the entire drug development and review process. 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, Breakthrough Therapy designated products are eligible for Priority Review, where the FDA has a goal to take action on an application within six months, as opposed to ten months under standard review. Breakthrough Therapy designation does not change the standards for approval.

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 17.3 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, investigational NMDA receptor antagonist with multimodal activity under development for the treatment of major depressive disorder and other central nervous system (CNS) disorders. AXS-05 consists 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, which is a novel mechanism of action, meaning it works differently than currently available therapies for depression. The dextromethorphan component of AXS-05 is also a sigma-1 receptor agonist, nicotinic acetylcholine receptor antagonist, and inhibitor of the serotonin and norepinephrine transporters. 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 30 issued U.S. and international patents which provide protection out to 2034. AXS-05 is 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 core CNS product candidate portfolio includes four clinical-stage candidates, AXS-05, AXS-07, AXS-09, and AXS-12. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD) and a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD). AXS-05 is also being developed for major depressive disorder (MDD) and smoking cessation treatment. AXS-07 is currently in a Phase 3 trial for the acute treatment of migraine. AXS-12 is currently in a Phase 2 trial in narcolepsy. The Axsome Pain and Primary Care business unit (Axsome PPC) houses Axsome's pain and primary care assets, including AXS-02 and AXS-06, and intellectual property which covers these and related product candidates and molecules being developed by Axsome and others. AXS-02 is being developed for osteoporosis, the pain of knee osteoarthritis, and chronic low back pain. AXS-06 is being developed for osteoarthritis and rheumatoid arthritis. AXS-02, AXS-05, AXS-06, AXS-07, AXS-09, and AXS-12 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.

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, 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 plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the ASCEND clinical trial 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; 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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AXSOME THERAPEUTICS

Axsome Therapeutics Announces Acceleration of MOMENTUM Phase 3 Trial of AXS-07 in Migraine

Topline results now anticipated in 2H 2019

Trial enriched with only patients with history of inadequate response to prior migraine treatments

Trial compares AXS-07 to placebo and active comparator

Trial being conducted under FDA Special Protocol Assessment (SPA)

Company to discuss development on the conference call scheduled today at 8:00 AM Eastern

NEW YORK, May 6, 2019 (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 acceleration of the timeline for reporting topline results from the MOMENTUM Phase 3 trial of AXS-07 (MoSEIC™ meloxicam and rizatriptan), Axsome's novel, oral, investigational medicine with distinct dual mechanisms of action for the acute treatment of migraine. The trial is being conducted pursuant to a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). The first patient was enrolled in the MOMENTUM trial in March 2019, and currently approximately 40% of the target number of patients have been randomized. Based on the faster-than-expected enrollment in this trial, topline results are now expected in the second half of 2019, versus previous guidance of the first quarter of 2020.

The MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 trial is a randomized, double-blind, placebo- and active-controlled study of AXS-07 for the acute treatment of migraine, in which patients are randomized to treatment with AXS-07, rizatriptan, meloxicam, or placebo. Rizatriptan, the active comparator in the trial, is considered to be one of the most efficacious oral medications currently available for the acute treatment of migraine [1].

Patients enrolled in the MOMENTUM trial must have a history of inadequate response to prior acute migraine treatments, assessed using the Migraine Treatment Optimization Questionnaire (mTOQ-4). The mTOQ-4 is a validated questionnaire that assesses efficacy response to prior acute treatments based on four aspects (two-hour pain freedom, efficacy for at least 24 hours with one dose, ability to plan daily activities, and disruption of daily activities) [2]. In addition to having a history of inadequate response, the majority of patients randomized to date in the MOMENTUM trial also report allodynia with their migraine attacks. Allodynia, which is pain from normally non-painful stimuli (such as brushing hair, wearing glasses, taking a shower, etc.), has been shown to be strongly associated with worse outcomes for pain freedom and pain relief after treatment with triptan medications [3,4].

The MOMENTUM trial is being enriched with difficult-to-treat patients because they represent a population for whom superior medicines are urgently needed. The rapid absorption and distinct dual mechanisms of action of AXS-07 provide a scientific rationale for potential success in providing relief for this more treatment resistant population. AXS-07 consists of MoSEIC™ meloxicam and rizatriptan. Meloxicam, a COX-2 preferential non-steroidal anti-inflammatory drug, is a new molecular entity for migraine enabled by Axsome's MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Rizatriptan is a potent 5-$HT_{1B/D}$ agonist.

"The stringent design of the MOMENTUM trial, which is enrolling a difficult-to-treat patient population and utilizing a potent active comparator, sets a high bar for the demonstration of efficacy of AXS-07," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Success in this trial would highlight the potentially differentiated efficacy profile of this novel, oral treatment with distinct dual mechanisms of action, designed to address the unmet medical needs in the acute treatment of migraine. We are pleased with the pace of enrollment and look forward to the results of the MOMENTUM trial, anticipated in the second half of 2019, which, if positive, would support the filing of an NDA for AXS-07 potentially as early as 2020."

Elements of the MOMENTUM Trial:

- Eligible patients are randomized in a 2:2:2:1 ratio to treatment with AXS-07, rizatriptan, meloxicam, or placebo. The target number of patients is approximately 875.
- Eligible patients must have a history of inadequate response to prior acute migraine treatments, assessed using the mTOQ-4 questionnaire.
- Co-primary endpoints are freedom from headache pain two hours after dosing, and freedom from the most bothersome migraine-associated symptom (nausea, photophobia, or phonophobia) two hours after dosing, for AXS-07 as compared to placebo.
- Superiority of AXS-07 to the rizatriptan and meloxicam arms (component contribution) will be established based on sustained freedom from headache pain from two to 24 hours after dosing.

The MOMENTUM study is being conducted pursuant to an SPA with the FDA. The SPA provides agreement that the overall MOMENTUM trial design (e.g., entry criteria, dose selection, endpoints) and planned analysis adequately address objectives that, if met, will support the regulatory submission for approval of AXS-07 for the indication of acute treatment of migraine in adults with or without aura.

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss the progress of the MOMENTUM Phase 3 trial in the acute treatment of migraine as well as AXS-05 in the treatment of major depressive disorder following a Breakthrough Therapy meeting with the FDA. 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 3977129. 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 the MOMENTUM Trial

MOMENTUM is a Phase 3, randomized, double-blind, multicenter, controlled trial to assess the efficacy and safety of AXS-07 in the acute treatment of migraine. Approximately 875 patients, with a history of inadequate response to prior migraine treatments, will be randomized in a 2:2:2:1 ratio to treatment with AXS-07, rizatriptan, meloxicam, or placebo. The two co-primary endpoints of the trial are the proportion of patients who are free from headache pain two hours after dosing, and the proportion of patients who no longer suffer from their most bothersome migraine-associated symptom (nausea, photophobia, or phonophobia) two hours after dosing, for AXS-07 as compared to placebo.

About Migraine

Over 37 million Americans suffer from migraine according to the Centers for Disease Control, and it is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. Migraine is characterized by recurrent attacks of pulsating, often severe and disabling head pain associated with nausea, and sensitivity to light and or sound. It is estimated that migraine accounts for $78 billion in direct (e.g. doctor visits, medications) and indirect (e.g. missed work, lost productivity) costs each year in the United States [5]. Published surveys of migraine sufferers indicate that more than 70% are not fully satisfied with their current treatment, that nearly 80% would try a new therapy, and that they desire treatments that work faster, more consistently, and result in less symptom recurrence [6,7].

About AXS-07

AXS-07 is a novel, oral, investigational medicine with distinct dual mechanisms of action under development for the acute treatment of migraine. AXS-07 consists of MoSEIC™ meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC (Molecular Solubility Enhanced Inclusion Complex) technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug and rizatriptan is a 5-$HT_{1B/D}$ agonist. AXS-07 is designed to provide rapid, enhanced and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is not approved by the FDA.

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2. Lipton RB, Fanning KM, Serrano D, Reed ML, Cady R, Buse DC. Ineffective acute treatment of episodic migraine is associated with new-onset chronic migraine. Neurology. 2015 Feb 17;84(7):688-95.

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4. Lipton RB, Munjal S, Buse DC, Fanning KM, Bennett A, Reed ML. Predicting Inadequate Response to Acute Migraine Medication: Results from the American Migraine Prevalence and Prevention (AMPP) Study. Headache. 2016 Nov;56(10):1635-1648.

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7. Lipton RB, Stewart WF. Acute migraine therapy: do doctors understand what patients with migraine want from therapy? Headache. 1999;39(suppl 2):S20-S26.

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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 plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the ASCEND clinical trial 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; 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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