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

Date of Report (Date of Earliest Event Reported): March 18, 2019

AERPIO PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38560**	**61-1547850**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9987 Carver Road
Cincinnati, OH **45242**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code (513) 985-1920

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events

On March 18, 2019, the Company issued a press release titled "Aerpio Pharmaceuticals Announces Results From TIME-2b Study of AKB-9778 in Diabetic Retinopathy." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 18, 2019.

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.

Date: March 18, 2019

AERPIO PHARMACEUTICALS, INC.

By: /s/ Stephen Hoffman, M.D., Ph.D.
Stephen Hoffman, M.D., Ph.D.
Chief Executive Officer

Aerpio Pharmaceuticals Announces Results From TIME-2b Study of AKB-9778 in Diabetic Retinopathy

TIME-2b Study Did Not Meet the Primary Endpoint of 2-Step Reduction in DRSS Score

Conference Call and Webcast Today, March 18th at 8:30 a.m. EDT

CINCINNATI – Mar. 18, 2019 — (BUSINESS WIRE) Aerpio Pharmaceuticals, Inc. (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, today announced top-line results from the Company's TIME-2b study, a Phase 2b clinical trial designed to assess the efficacy and safety of Aerpio's lead candidate, AKB-9778, for patients with moderate to severe non-proliferative diabetic retinopathy (NPDR).

Administration of AKB-9778 twice daily did not meet the study's primary endpoint of the percentage of patients with an improvement of two or more steps in the study eye diabetic retinopathy severity score (DRSS) compared to placebo. The percentage of patients achieving this endpoint for AKB-9779 twice daily (BID) and placebo were 9.6% and 3.8%, respectively (p=0.270). In all qualified eyes (i.e., study eyes and fellow eyes that met the inclusion/exclusion criteria), the percentage of eyes achieving this endpoint was 8.6% and 2.7%, for AKB-9778 BID and placebo, respectively (p=0.158). The rates of progression to sight-threatening complications, including diabetic macular edema (DME) and/or proliferative diabetic retinopathy (PDR), during the 48-week treatment period were similar between treatment groups.

AKB-9778 did show encouraging data in a number of prespecified, key secondary endpoints, consistent with the observations in the prior Phase 2a (TIME-2) trial, including changes in Urine Albumin-Creatinine Ratio (UACR), a measure of kidney function, and in intraocular pressure (IOP). The company plans to advance a topical drop formulation of AKB-9778 into clinical development and expects to initiate a Phase 1b study in the second quarter of 2019 with results anticipated by the end of 2019.

AKB-9778 was found to be safe and well-tolerated in this patient population through 48 weeks of twice-daily dosing. The most common adverse events with higher incidence in the AKB-9778 BID group were dizziness of 10.9% versus 7.0% in the placebo arm, and headache of 10.9% compared to placebo of 3.5%. There was one death in the study, and it was in the placebo group.

"While we are disappointed in the primary endpoint results of this study, we are nevertheless encouraged by the fact that several other promising findings observed in our prior 3-month Phase 2a trial have been prospectively confirmed in this 1-year trial," said Stephen Hoffman, M.D.,

Ph.D., Chief Executive Officer of Aerpio. “We and our clinical advisors believe that collectively these data support a potentially important role of the Tie2 pathway for the treatment of diabetic complications, as well as for open angle glaucoma. After a full analysis of the study data we plan to provide an update on the status of the NPDR program. We would like to thank the patients and investigators that participated in this trial.”

TIME-2b Study Design

The TIME-2b study was a double-masked, placebo-controlled, multi-center trial designed to evaluate the effect of AKB-9778 in patients with moderate-to-severe NPDR. 167 patients were randomized to receive 48 weeks of treatment with either AKB-9778 15 mg subcutaneously once daily (and placebo subcutaneously once daily), AKB-9778 15 mg subcutaneously twice daily, or placebo subcutaneously twice daily. The primary endpoint of the TIME-2b study was the percentage of patients who improved by two or more steps in DRSS in the study eye. One of the study’s secondary objectives, the urine albumin to creatinine ratio or UACR, was prospectively included based on a post-hoc analysis of this biomarker in the TIME-2 Phase 2a clinical trial of AKB-9778 in diabetic macular edema.

Conference Call and Webcast

Aerpio management will host a live conference call and webcast at 8:30 a.m. EDT today to discuss the results from the TIME-2b study.

The live webcast and a replay may be accessed by visiting Aerpio’s website at http://ir.aerpio.com/. Please connect to the Company’s website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (877) 216-7943 (U.S.) or (417) 629-5045 (international) to listen to the live conference call. The conference ID number for the live call is 6978348. Please dial in approximately 10 minutes prior to the call. Telephone replay will be available approximately two hours after the call. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID number for the replay is 6978348.

About AKB-9778

AKB-9778 is being developed as a subcutaneous injection for the treatment of non-proliferative diabetic retinopathy and as an eyedrop formulation for the treatment of glaucoma. AKB-9778 binds to and inhibits vascular endothelial protein tyrosine phosphatase (VE-PTP), an important negative regulator of Tie2. Decreased Tie2 activity contributes to vascular instability in many diseases including diabetes. AKB-9778 activates the Tie2 receptor irrespective of extracellular levels of its binding ligands, angiopoietin-1 (agonist) or angiopoietin-2 (antagonist) and may be the most efficient pharmacologic approach to maintain normal Tie2 activation.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class compounds that activate Tie2 to treat ocular diseases and complications of diabetes. Tie2 is an

important regulator of vascular stability and its down-regulation is found in patients with diabetes. Down-regulation is caused by activation of two inhibitors of Tie2, VE-PTP and Ang-2 due to hypoxia or tissue ischemia. The Company's lead compound, AKB-9778, is a systemically-administered small molecule activator of the Tie2 pathway (via highly selective and potent deactivation of VE-PTP) and is in clinical development for the treatment of non-proliferative diabetic retinopathy. AKB-9778 is also being investigated for its potential utility in treating diabetic nephropathy and an eyedrop formulation is in development as a potential treatment for open-angle glaucoma. For more information, please visit www.aerpio.com

Forward Looking Statements

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the development of the Company's product candidates, including AKB-9778, the Company's plans for future development of its product candidates, the potential of the Tie2 pathway in treatment of diabetic complications, and the therapeutic potential of the Company's product candidates. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the ability to raise the additional funding needed to continue to develop AKB-9778 or other product development plans, the inherent uncertainties associated with the drug development process, including uncertainties in regulatory interactions, commencing clinical trials and enrollment of patients in clinical trials, competition in the industry in which the Company operates and overall market conditions.

These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

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