

**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): October 10, 2019

AERPIO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38560
(Commission
File Number)

61-1547850
(I.R.S. Employer
Identification No.)

9987 Carver Road
Cincinnati, OH
(Address of principal executive offices)

45242
(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))

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, \$0.0001 par value per share	ARPO	Nasdaq Capital Market

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 October 10, 2019, Aerpio Pharmaceuticals, Inc. issued a press release titled “Aerpio Pharmaceuticals Announces Interim Results from its Phase 1b Clinical Trial of Topical Ocular Formulation of AKB-9778 for Primary Open Angle Glaucoma.” 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Aerpio Pharmaceuticals, Inc. on October 10, 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: October 10, 2019

AERPIO PHARMACEUTICALS, INC.

By: /s/ Stephen Hoffman

Stephen Hoffman

Chief Executive Officer



Aerpio Pharmaceuticals Announces Interim Results from its Phase 1b Clinical Trial of Topical Ocular Formulation of AKB-9778 for Primary Open Angle Glaucoma

CINCINNATI - October 10, 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 interim results from its Phase 1b clinical trial of a topical ocular formulation of AKB-9778 in development as a potential treatment for primary open angle glaucoma (POAG).

The Phase 1b study is an ongoing randomized, double masked study designed to assess increasing concentrations of AKB-9778 dosed topically as eye drops (5mg/ml QD, 15 mg/ml QD, 40 mg/ml QD and 40 mg/ml BID) in 4 sequential cohorts of 12 subjects, randomized 3:1 to receive AKB-9778 or placebo, for 7 days. The primary outcome of the study is ocular safety and tolerability with change in intraocular pressure (IOP) as a pharmacodynamic outcome. Conjunctival hyperemia grade and IOP were assessed prior to dosing and at 2-, 4- and 8-hours post-dose on Day 1 and Day 7. The unmasked interim analysis was limited to the first three cohorts (5 mg/ml QD, 15 mg/ml QD, 40 mg/ml QD). Topical ocular administration of AKB-9778 was well tolerated over 7 days at all dose levels for the first three cohorts. Compared to placebo, there was a dose dependent increase in minimal to mild conjunctival hyperemia with AKB-9778, which was transient and generally considered non-adverse. There was also a time and dose dependent reduction in IOP that, in the highest QD dose cohort peaked at 4 hours post-dose (-1.47 mmHg; $p = 0.041$)/-10.64%; $p = 0.027$) and was sustained through eight hours on day 7, returning to baseline levels at 24 hours post-dose. Based on these interim results, the Phase 1b protocol has been amended to include patients with ocular hypertension and POAG to further assess safety and activity on IOP in the target patient population. The Company expects to announce full results of the ongoing Phase 1b study in the first quarter of 2020.

“We are encouraged by the early safety findings and potential efficacy signal of this ongoing Phase 1b trial,” said Kevin Peters, M.D., Chief Scientific Officer of Aerpio Pharmaceuticals. “The conventional outflow tract is responsible for the majority of fluid drainage from the front of the eye, which is critical for maintaining normal IOP and is often the site of pathology implicated in the increased IOP in patients suffering from POAG. Recent mouse and human genetic data establish a key role for the Tie2 pathway in the development and maintenance of Schlemm’s canal, a key component of the conventional outflow tract. AKB-9778, a potent small molecule Tie2 activator, has shown IOP lowering effects after subcutaneous administration in two sequential Phase 2 studies in patients with diabetic retinopathy and normal IOP. We now look forward further to evaluating AKB-9778’s safety and activity on IOP in patients with ocular hypertension and POAG.”

About AKB-9778

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 and other conditions. Down-regulation is caused by activation of two inhibitors of Tie2, VE-PTP and Ang-2. The Company's lead compound, AKB-9778, is being investigated, in a topical drop formulation, for its potential as a 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, including the timing of the Company's planned clinical trials and expected results from such clinical trials, 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 continue to develop AKB-9778 or other product candidates, the inherent uncertainties associated with the drug development process, including uncertainties in regulatory interactions, commencing clinical trials and enrollment of patients in clinical trials, and 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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Source: Aerpio Pharmaceuticals, Inc.