

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): May 9, 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))

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.

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

Item 2.02 Results of Operations and Financial Condition

On May 9, 2019, Aerpio Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release issued by Aerpio Pharmaceuticals, Inc. on May 9, 2019 furnished herewith.</u>

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: May 9, 2019

AERPIO PHARMACEUTICALS, INC.

By: /s/ Stephen Hoffman

Stephen Hoffman

Chief Executive Officer



Aerpio Reports First Quarter 2019 Financial Results and Provides Business Update

On Track to Initiate Phase 1b Clinical Trial of Topical Drop Formulation of AKB-9778 for Primary Open-Angle Glaucoma (POAG) in the Second Quarter of 2019

CINCINNATI—(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 reported financial results for the first quarter ended March 31, 2019, and provided a business update.

“Although the TIME-2b study of the Tie2 activator, AKB-9778, did not meet its primary endpoint in non-proliferative diabetic retinopathy (NPDR), we continue to be encouraged by pre-specified secondary endpoint data that suggest the potential for AKB-9778 to treat primary open-angle glaucoma (POAG) and possibly diabetic nephropathy,” said Stephen Hoffman, M.D., Ph.D., Chief Executive Officer of Aerpio. “In the near-term, our top priority is the development of our topical drop formulation of AKB-9778 for POAG, for which we expect to begin a Phase 1b clinical trial this quarter, with data anticipated by the end of the year. Our glaucoma program, combined with our license with Gossamer Bio, Inc. for GB004, a hypoxia inducible factor (HIF)-1 alpha stabilizer in clinical development for inflammatory bowel disease, represent two promising clinical-stage programs, each with near-term milestones. Additionally, we have reduced our company expenses and are committed to moving forward in a capital-efficient manner. Based on our current development plans, we have sufficient capital to fund our operations through at least the second quarter of 2021.”

Recent Company Highlights and Upcoming Milestones

- Announced top-line results of the TIME-2b clinical trial designed to evaluate the safety and efficacy of AKB-9778, a Tie2 activator, in NPDR; the study did not meet its primary endpoint; however, the study generated encouraging data in a number of prespecified, key secondary endpoints, including reductions in urine albumin-to-creatinine ratio (UACR), a measure of kidney function, suggesting potential utility as a treatment for diabetic nephropathy, and reductions in intraocular pressure (IOP), suggesting potential utility in open-angle glaucoma;
- Presented encouraging preliminary IOP data from the Company’s TIME-2b study at the Association for Research in Vision and Ophthalmology Annual Meeting 2019; and,

- Anticipate initiating a Phase 1b clinical trial to evaluate the safety and pharmacokinetics of a topical drop formulation of AKB-9778 in healthy subjects in the second quarter of 2019, with results anticipated by the end of 2019.

First Quarter 2019 Financial Highlights

As of March 31, 2019, cash and cash equivalents totaled \$53.4 million, compared to \$62.6 million as of December 31, 2018. Total shares outstanding, as of March 31, 2019, were 40.6 million.

For the three months ended March 31, 2019, operating expenses totaled \$8.8 million, including \$0.6 million in non-cash stock compensation expense, compared to \$7.5 million, including \$1.1 million in non-cash stock compensation expense, for the same period in 2018.

Research and development expenses for the three months ended March 31, 2019, increased \$1.6 million, or 39%, compared to the same period in 2018. This increase was primarily the result of increased expenses associated with the TIME-2b clinical trial of AKB-9778.

General and administrative expenses for the three months ended March 31, 2019, decreased \$0.2 million, or 6%, compared to the same period in 2018. This decrease was primarily attributable to decreased stock-based compensation costs.

Net loss attributable to common shareholders for the three months ended March 31, 2019 was \$8.5 million, or \$0.21 per share, compared to a net loss attributable to common shareholders of \$7.4 million, or \$0.27 net loss per share, for the same period in 2018.

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

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, angiotensin-1 (agonist) or angiotensin-2 (antagonist) and may be the most efficient pharmacologic approach to maintain normal Tie2 activation.

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, projections regarding future revenue and financial performance, the Company's long-term growth, 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 and commencement of the Company's planned clinical trials and expected results from such clinical trials, the therapeutic potential of the Company's product candidates, and the Company's collaboration with Gossamer Bio. 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, our ability to realize the intended benefits of our collaboration with Gossamer Bio, 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.

AERPIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,423	\$ 62,614
Prepaid research & development contracts	340	754
Other current assets	536	616
Total current assets	54,299	63,984
Furniture and equipment, net	199	99
Operating lease right-of-use asset	518	—
Deposits	41	41
Total assets	<u>\$ 55,057</u>	<u>\$ 64,124</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,734	\$ 5,457
Current portion of operating lease liability	190	—
Total current liabilities	3,924	5,457
Operating lease liability, net of current portion	338	—
Total liabilities	4,262	5,457
Stockholders' equity:		
Capital	178,253	177,626
Accumulated deficit	(127,458)	(118,959)
Total stockholders' equity	50,795	58,667
Total liabilities and stockholders' equity	<u>\$ 55,057</u>	<u>\$ 64,124</u>

AERPIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Three months ended	
	March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 5,586	\$ 4,029
General and administrative	3,255	3,448
Total operating expenses	<u>8,841</u>	<u>7,477</u>
Interest and other income	348	51
Net and comprehensive loss	<u>\$ (8,493)</u>	<u>\$ (7,426)</u>
Net and comprehensive loss per share basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.27)</u>
Weighted average number of common shares used in computing net and comprehensive loss per share, basic and diluted	<u>40,588</u>	<u>27,046</u>

Contacts**Investor & Media:****Aerpio Pharmaceuticals, Inc.**

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or

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or

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Source: Aerpio Pharmaceuticals, Inc.