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 16, 2020

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))

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 2.02 Results of Operations and Financial Condition

On March 16, 2020, Aerpio Pharmaceuticals, Inc. announced its financial results for its fourth quarter and year ended December 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information under Item 2.02 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

Exhibit No.	Description
99.1	Press release issued by Aerpio Pharmaceuticals, Inc., on March 16, 2020 furnished herewith.

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 16, 2020

AERPIO PHARMACEUTICALS, INC.

By: /s/ Joseph Gardner, Ph.D.
Joseph Gardner
President and Founder

Exhibit 99.1

Aerpio Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

Plan to advance AKB-9778 topical formulation into a Phase 2 trial in open angle glaucoma with top line results expected during the first quarter of 2021

Conference Call and Webcast Today, March 16, 2020 at 8:30 a.m. EST

CINCINNATI, Ohio, March 16, 2020 – Aerpio Pharmaceuticals, Inc. ("Aerpio") (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 fourth quarter and full year ended December 31, 2019.

"We ended the year with a strong cash position, $38.5 million, and with promising results in our Phase 1b glaucoma clinical trial," said Joseph Gardner, Ph.D., President and Founder of Aerpio. "A mean reduction in intraocular pressure of 1.58 mmHg on top of standard of care prostaglandins, was observed in cohort five which included patients with ocular hypertension (OH) and primary open angle glaucoma patients (OAG). The mean intraocular pressure (IOP) reduction was statistically significant after only 7 days of dosing and the tolerability was favorable with minimal hyperemia. These results set us up to run a Phase 2 trial starting in the third quarter of this year. We have reviewed the study results with glaucoma experts who support moving forward with further development. Once initiated, we expect topline results from this trial to read out in the first quarter of 2021."

2019 Company Highlights

- Completed a Phase 1b clinical trial designed to assess the safety of the Company's lead candidate, AKB-9778 in the form of topical ocular drops, for patients with OAG and OH.
- Presented promising IOP lowering data from the Company's Phase 1b clinical trial of topical ocular formulation of AKB-9778 in patients with OAG and OH in February 2020 at the Glaucoma 360 conference in San Francisco. The IOP lowering activity observed in the Phase 1b trial when AKB-9778 was combined with a prostaglandin appeared comparable to or better than published Phase 3 data for marketed adjuvant therapies.
- Restructured the Company to preserve cash and provide flexibility to explore potential strategic alternatives.

- Completed a Phase 2b study in diabetic retinopathy that demonstrated activity in prespecified secondary diabetic endpoints, most notably a urinary albumin creatine ratio (UACR) signal for diabetic nephropathy.

Fourth Quarter and Full Year 2019 Financial Highlights

As of December 31, 2019, cash and cash equivalents totaled $38.5 million.

Revenue for the full year ended December 31, 2019, was $0 compared to $20.2 million for the full year ended December 31, 2018. Revenue for the full year ended December 31, 2018 was primarily attributable to the $20.0 million up front payment from Gossamer Bio., Inc. related to Aerpio's license of AKB-4924 to Gossamer Bio., Inc's subsidiary GB004 in June 2018.

For the three months ended December 31, 2019, operating expenses totaled $4.7 million, compared to $8.9 million for the same period in 2018. Operating expenses for the full year ended December 31, 2019, was $24.4 million compared to $31.3 million for the full year ended December 31, 2018.

Research and development expenses for the three months ended December 31, 2019, decreased approximately $3.1 million, or 59.4%, to $2.1 million from $5.2 million in the three months ended December 31, 2018. Research and development expenses for the full year ended December 31, 2019, decreased approximately $5.0 million, or 28.2%, to $12.8 million from $17.8 million in the full year ended December 31, 2018. This decrease was primarily the result of decreased expenses associated with our clinical programs.

General and administrative expenses for the three months ended December 31, 2019, decreased approximately $2.1 million, or 57.4%, to $1.5 million from $3.6 million, in the three months ended December 31, 2018. General and administrative expenses for the full year ended December 31, 2019, decreased approximately $3.7 million, or 27.7%, to $9.8 million from $13.5 million in the full year ended December 31, 2018. This decrease was primarily attributable to decreased stock compensation, headcount reductions and general office expenses.

Restructuring expense for the year ended December 31, 2019 of $1.9 million was the result of a reduction of headcount during the second and fourth quarters of 2019.

Net loss attributable to common stockholders for the three months ended December 31, 2019, was $4.4 million, or $0.11 per share, compared to a net loss attributable to common stockholders of $8.5 million, or $0.21 per share, for the three months ended December 31, 2018. Net loss attributable to common stockholders for the full year ended December 31, 2019, was $23.3 million, or $0.57 per share compared to a net loss attributable to common stockholders of $10.4 million, or $0.31 per share, for the full year ended December 31, 2018.

Conference Call and Webcast

Aerpio management will host a live conference call and webcast at 8:30 a.m. EST today to discuss Aerpio's financial results and provide a general business update.

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 877-407-9716 (U.S.) or 201-493-6779 (international) to listen to the live conference call. The conference ID number for the live call is 13700254. Please dial in approximately 10 minutes prior to the call. A replay of the call will be available via webcast at http://public.viavid.com/index.php?id=138519.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications. Recently published mouse and human genetic data implicate the Angpt/Tie2 pathway in maintenance of Schlemm's canal, a critical component of the conventional outflow tract. The Company's lead compound, AKB-9778, a first-in-class small molecule inhibitor of vascular endothelial protein tyrosine phosphatase ("VE-PTP"), is being developed as a potential treatment for open angle glaucoma, and the Company intends to investigate the therapeutic potential of AKB-9778 in other indications. The Company is also evaluating development options for ARP-1536, a humanized monoclonal antibody, for its therapeutic potential in the treatment of diabetic vascular complications including nephropathy and diabetic macular edema ("DME"). The Company's third asset is a bispecific antibody that binds both VEGF and VE-PTP which is designed to inhibit VEGF activation and activate Tie2. This bispecific antibody has the potential to be an improved treatment for wet age-related macular degeneration and DME via intravitreal injection. Finally, the Company has exclusively out-licensed AKB-4924 (now called GB004), a first-in-class small molecule inhibitor of hypoxia-inducible factor-1 (HIF). GB004 is being developed by AKB-4924's exclusive licensor, Gossamer Bio, Inc. (Nasdaq: GOSS), in return for an upfront payment of $20 million, future potential development, regulatory, and sales milestones of up to $400 million, and royalties on worldwide net sales. 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 and more recently has been shown to contribute to the development of increased IOP and glaucoma. 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. Aerpio is studying a topical ocular formulation of AKB-9778 in open angle glaucoma and exploring the utility of subcutaneous AKB-9778 for diabetic complications, including diabetic nephropathy.

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 Company's product candidates, including AKB-9778, ARP-1536 and the bispecific antibody asset, the clinical development plan therefor and the therapeutic potential thereof, the Company's strategic alternatives review process and the potential transactions that

may be identified and explored as a result of that process, and the intended benefits from its collaboration with Gossamer Bio, Inc. for GB004. 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, the design of planned or future clinical trials, commencing clinical trials and enrollment of patients in clinical trials; the ability to identify and consummate strategic alternatives that yield additional value for shareholders; the timing, benefits and outcome of the Company's strategic alternatives review process, including the determination of whether or not to pursue or consummate any strategic alternative; the structure, terms and specific risks and uncertainties associated with any potential strategic transaction; potential disruptions in our business and the stock price as a result of our exploration, review and pursuit of strategic alternatives or the public announcement thereof and any decision or transaction resulting from such review; and competition in the industry in which the Company operates and overall market conditions; and the additional factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, as updated by our subsequent Quarterly Reports on Form 10-Q and our other subsequent filings with the SEC.

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)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 38,525	$ 62,614
Prepaid research and development contracts	311	754
Other current assets	735	616
Total current assets	39,571	63,984
Furniture and equipment, net	164	99
Operating lease right-of-use assets, net	162	—
Deposits	40	41
Total assets	$ 39,937	$ 64,124
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,232	$ 5,457
Current portion of operating lease liability	103	—
Total current liabilities	3,335	5,457
Operating lease liability, net of current portion	67	—
Total liabilities	3,402	5,457
Stockholders' equity:		
Capital	178,771	177,626
Accumulated deficit	(142,236)	(118,959)
Total stockholders' equity	36,535	58,667
Total liabilities and stockholders' equity	$ 39,937	$ 64,124

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

	Three months ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
License revenue, and other	$ —	$ 2	$ —	$ 20,157
Operating expenses:				
Research and development	2,129	5,249	12,824	17,853
General and administrative	1,541	3,619	9,756	13,486
Restructuring expense	987	—	1,864	—
Total operating expenses	4,657	8,868	24,444	31,339
Loss from operations	(4,657)	(8,866)	(24,444)	(11,182)
Interest and other income	211	348	1,173	785
Net and comprehensive loss	$ (4,446)	$ (8,518)	$(23,271)	(10,397)
Net loss per common share basic and diluted	$ (0.11)	$ (0.21)	$ (0.57)	$ (0.31)
Weighted average common shares outstanding Basic and diluted	40,588	40,588	40,588	33,931

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