Aerpio Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

March 5, 2019

Top-Line Results from the TIME-2b Clinical Trial Evaluating the Effect of AKB-9778 in Patients with Non-Proliferative Diabetic Retinopathy (NPDR) Expected in March 2019

Conference Call and Webcast Today, March 5th at 8:30 a.m. EST

CINCINNATI--(BUSINESS WIRE)--Mar. 5, 2019-- 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 fourth quarter and full year ended December 31, 2018.

“We remain on track to report top-line data from our TIME-2b clinical trial before the end of March,” said Stephen Hoffman, M.D., Ph.D., Chief Executive Officer of Aerpio. “We view the study as an important inflection point for Aerpio and expect to use the results to direct the future development of AKB-9778 in non-proliferative diabetic retinopathy and possibly other conditions associated with diabetes. We look forward to sharing the results with you later this month. In parallel with our TIME-2b clinical trial, we continue to advance a topical ocular formulation of AKB-9778 in open angle glaucoma and expect to initiate a Phase 1b study in the second quarter of 2019.”

2018 Company Highlights

- Completed dosing of the TIME-2b study, a Phase 2b clinical trial designed to assess the efficacy and safety of the Company’s lead candidate, AKB-9778, for patients with moderate-to-severe non-proliferative diabetic retinopathy (NPDR);
- Presented promising preliminary renal function data from the Company’s TIME-2 Phase 2a clinical trial of AKB-9778 in diabetic retinopathy patients at the American Society of Nephrology Kidney Week 2018;
- Announced, in June 2018, an exclusive global license agreement with a wholly-owned subsidiary of Gossamer Bio, Inc., GB004, Inc. (“Gossamer”), for the development and commercialization of Aerpio’s HIF-1 alpha stabilizer, AKB-4924 (renamed GB004 by Gossamer), along with other related compounds. Under the terms of the license agreement, Aerpio received a $20 million up front payment, and is eligible to receive potential development, regulatory, and sales milestones of up to $400 million, and royalties on worldwide net sales, which range from a high single digit to mid-teen percentage of net sales. Gossamer will be responsible for the remaining development, regulatory, and commercialization expenses for GB004;
- Completed an underwritten public offering of its common stock, resulting in approximately $48.1 million in net proceeds, also in June of 2018. Concurrent with the financing, Aerpio began trading on the Nasdaq Capital Market.

Fourth Quarter and Full Year 2018 Financial Highlights

As of December 31, 2018, cash and cash equivalents totaled $62.6 million. Total shares outstanding as of December 31, 2018 were 40.6 million.

Revenue for the full year ended December 31, 2018 of $20.2 million is primarily attributable to the $20.0 million up front payment from Gossamer related to Aerpio’s license to Gossamer of AKB-4924 in June 2018.

For the three months ended December 31, 2018, operating expenses totaled $8.9 million, compared to $6.3 million for the same period in 2017. Operating expenses for the full year ended December 31, 2018, was $31.3 million compared to $21.4 million for the full year ended December 31, 2017.

Research and development expenses for the full year ended December 31, 2018, increased approximately $5.7 million, or 47.0%, to $17.9 million from $12.1 million in the full year ended December 31, 2017. This increase was primarily the result of increased and ongoing expenses associated with the Phase 2b trial of AKB-9778.

General and administrative expenses for the full year ended December 31, 2018, increased approximately $4.2 million, or 45.9%, to $13.5 million from $9.2 million in the full year ended December 31, 2017. This increase was primarily attributable to increased personnel-related expenses.

Net loss attributable to common stockholders for the three months ended December 31, 2018 was $8.5 million, or $0.21 per share, compared to a net loss attributable to common stockholders of $6.2 million, or $0.23 per share, for the same period in 2017. Net loss attributable to common stockholders for the full year ended December 31, 2018 was $10.4 million, or $0.31 per share compared to a net loss attributable to common stockholders of $22.3 million, or $1.03 per share, for the full year ended December 31, 2017.

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) 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 4778807. 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 4778807.

About AKB-9778

AKB-9778 is being developed as a subcutaneous injection for the treatment of non-proliferative diabetic retinopathy. 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 Diabetic Retinopathy

Diabetic retinopathy (DR) is a complication of diabetes caused by damage to blood vessels in the retina, and occurs in roughly one of three patients with diabetes, and in those, in both eyes approximately 75% of the time. Severity of DR ranges from mild non-proliferative diabetic retinopathy to more advanced proliferative diabetic retinopathy, the hallmark of which is the development of new abnormal blood vessels. DR is the leading cause of blindness among working aged adults around the world, affecting roughly 140 million diabetics globally.

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 for non-proliferative diabetic retinopathy or otherwise and other pipeline candidates, the announcement of top-line results from the Company's TIME-2b clinical trial, the therapeutic potential of the Company's product candidates, including AKB-9778, and the Company's collaboration with Gossamer. 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 FDA and drug development process, the risk that we may not realize the intended benefits of our collaboration with Gossamer, 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)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 62,614	$ 20,264
Prepaid R&D contracts	754	313
Other current assets	616	323
Total current assets	63,984	20,900
Furniture and equipment, net	99	107
Deposits	41	21
Total assets	$ 64,124	$ 21,028
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,457	$ 3,592
Total current liabilities	5,457	3,592
Stockholders' equity:		
Capital	177,626	125,999
Accumulated deficit	(118,959)	(108,563)

Total stockholders' equity	58,667	17,436
Total liabilities and stockholders' equity	$ 64,124	$ 21,028

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

	Three months ended December 31,		Twelve months ended December 31,	
	2018	**2017**	**2018**	**2017**
License revenue, and other	$ 2	$ -	$ 20,157	$ -
Operating expenses:				
Research and development	5,249	3,780	17,853	12,147
General and administrative	3,619	2,509	13,486	9,242
Total operating expenses	8,868	6,289	31,339	21,389
Loss from operations	(8,866)	(6,289)	(11,182)	(21,389)
Interest and other income (expense), net	348	54	785	(12)
Net and comprehensive loss	(8,518)	(6,235)	(10,397)	(21,401)
Adjustment of convertible preferred stock	-	-	-	(943)
Net loss attributable to common shareholders	$ (8,518)	$ (6,235)	$ (10,397)	$ (22,344)
Net loss per common share basic and diluted	$ (0.21)	$ (0.23)	$ (0.31)	$ (1.03)
Weighted average common shares outstanding Basic and Diluted	40,588	26,965	33,931	21,673

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