Aerpio Reports Third Quarter 2018 Financial Results and Provides Business Update

November 7, 2018

TIME-2b Clinical Trial of AKB-9778 in Patients with Diabetic Retinopathy On Track

Conference Call and Webcast Today, November 7th at 8:30 a.m. EST

CINCINNATI--(BUSINESS WIRE)--Nov. 7, 2018-- 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 third quarter ended September 30, 2018 and provided a business update.

“Our TIME-2b clinical trial, evaluating the effect of AKB-9778, our first-in-class systemically administered Tie2 activator in patients with non-proliferative diabetic retinopathy (NPDR), is on track and we look forward to reporting top-line results in early Q2 2019,” commented Stephen Hoffman, M.D., Ph.D., Chief Executive Officer of Aerpio. “In addition to the progress we’ve made with AKB-9778 for NPDR, we continue to advance a topical ocular formulation of AKB-9778 in open angle glaucoma and expect to initiate a Phase 1b study in Q2 2019. We are also excited about the potential of AKB-4924 (now known as GB004) and our partnership with Gossamer Bio, as announced in June. On the financial front, we remain well capitalized following the completion of a successful $52 million financing in June and receipt of the $20 million up front payment from our partnership with Gossamer.”

TIME-2b Study Overview

The TIME-2b study is a double-masked, placebo-controlled, multi-center trial evaluating the effect of AKB-9778 in patients with 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 is the percentage of patients who improve by 2 or more steps in diabetic retinopathy severity score (DRSS) in the study eye. One of our 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. Initial results from this trial are expected early in the second quarter of 2019.

Third Quarter 2018 Financial Highlights

As of September 30, 2018, cash and cash equivalents totaled $68.8 million, compared to $20.3 million as of December 31, 2017. Total common shares outstanding as of September 30, 2018, were 40.6 million.

Revenue for the three and nine months ended September 30, 2018 of $18.8 million and $20.2 million, respectively, which is primarily attributable to the $20.0 million up front payment from Gossamer related to Aerpio’s license to Gossamer of AKB-4924. Based on the terms of the license agreement and applicable accounting guidance, the $20.0 million was recognized over a ninety-day performance period beginning June 25, 2018.

For the three months ended September 30, 2018, operating expenses totaled $7.6 million, including $0.8 million in non-cash stock compensation expense, compared to $4.8 million, including $0.1 million in non-cash stock compensation expense, for the same period in 2017. For the nine months ended September 30, 2018, operating expenses totaled $22.5 million, including $2.8 million in non-cash stock compensation expense, compared to $15.1 million, including $0.4 million in non-cash stock compensation expense, for nine months ended September 30, 2017.

Research and development expenses for the three months ended September 30, 2018, increased $1.4 million, or 48%, compared to the same period in 2017. Research and development expenses for the nine months ended September 30, 2018, increased $4.2 million, or 51%, compared to the nine months ended September 30, 2017. This increase in both periods was primarily the result of increased and ongoing expenses associated with the Phase 2b trial of AKB-9778.

General and administrative expenses for the three months ended September 30, 2018, increased $1.5 million, or 81%, compared to the same period in 2017. General and administrative expenses for the nine months ended September 30, 2018, increased $3.1 million, or 47%, compared to the nine months ended September 30, 2017. This increase in both periods was primarily attributable to increased stock-based compensation and personnel-related costs.

Net income attributable to common shareholders for the three months ended September 30, 2018 was $11.5 million, or $0.28 earnings per share, compared to a net loss attributable to common shareholders of $4.6 million, or $0.17 net loss per share, for the same period in 2017. Net loss attributable to common shareholders for the nine months ended September 30, 2018 was $1.9 million, or $0.06 net loss per share, compared to a net loss attributable to common shareholders of $16.1 million, or $0.81 net loss per share, for the nine months ended September 30, 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 4090026. 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 4090026.

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, projections regarding future revenue and financial performance, the Company's long-term growth, the development of the Company's product candidates, including AKB-9778 for non-proliferative diabetic retinopathy or otherwise, including the expected timing of results from the Company's TIME-2b clinical trial and the therapeutic potential of the Company's product candidates, including AKB-9778. 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, 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)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 68,807	$ 20,264
Prepaid R&D contracts	337	313
Other current assets	896	323
Total current assets	70,040	20,900
Furniture and equipment, net	101	107
Deposits	21	21
Total assets	$ 70,162	$ 21,028
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,645	$ 3,592
Total current liabilities	3,645	3,592
Stockholders' equity:		
Capital	176,958	125,999
Accumulated deficit	(110,441)	(108,563)
Total stockholders' equity	66,517	17,436
Total liabilities and stockholders' equity	$ 70,162	$ 21,028

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
License revenue, and other	$ 18,822	$ -	$ 20,155	$ -
Operating expenses:				

Research and development	4,346	2,942	12,604	8,367
General and administrative	3,278	1,814	9,866	6,733
Total operating expenses	7,624	4,756	22,470	15,100
Income (loss) from operations	11,198	(4,756)	(2,315)	(15,100)
Interest and other income (expense), net	339	107	437	(66)
Net and comprehensive income (loss)	11,537	(4,649)	(1,878)	(15,166)
Adjustment of convertible preferred stock	-	-	-	(943)
Net income (loss) attributable to common shareholders	$ 11,537	$ (4,649)	$ (1,878)	$ (16,109)
Net income (loss) per common share basic and diluted	$ 0.28	$ (0.17)	$ (0.06)	$ (0.81)
Weighted average common shares outstanding				
Basic	40,528	26,927	31,687	19,900
Diluted	40,962	26,927	31,687	19,900

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Source: Aerpio Pharmaceuticals, Inc.

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