

Aerpio Reports First Quarter 2018 Financial Results and Provides Company Update

May 15, 2018

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

CINCINNATI--(BUSINESS WIRE)--May 15, 2018-- Aerpio Pharmaceuticals, Inc. (OTCQB:ARPO), a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases, today reported financial results for the first quarter ended March 31, 2018.

Stephen Hoffman, M.D. Ph.D., Chief Executive Officer of Aerpio, commented, "We are pleased that TIME-2b, our ongoing Phase 2b study in patients with non-proliferative diabetic retinopathy (NPDR), is fully enrolled ahead of schedule. This study will evaluate the effect of daily AKB-9778, our first-in-class Tie2-activator, to improve the diabetic retinopathy severity score by two-steps or greater versus a placebo control after 48 weeks of treatment. We will also assess the number of patients that progress to diabetic macular edema and proliferative diabetic retinopathy, and kidney function as key secondary endpoints. We expect to report top-line data from the TIME-2b study in the second quarter of 2019."

Dr. Hoffman added, "In addition to our lead development program for NPDR, we continue to advance our earlier pipeline programs, a topical formulation of AKB-9778 in glaucoma and AKB-4924, our first-in-class HIF-1 α stabilizer, in inflammatory bowel disease. We are looking forward to multiple clinical milestones over the next twelve months."

Recent Company Highlights

- Completed enrollment in 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 NPDR.
- Presented top-line renal function data from the Company's Phase 2a TIME-2 clinical trial at the Keystone Symposium on Reducing the Burden of Diabetes Related End-Organ Injury in February 2018.
- Completed a pre-IND meeting with the U.S. Food and Drug Administration (FDA) for AKB-4924, a once-daily, oral HIF-1α stabilizer for treatment of ulcerative colitis, a form of inflammatory bowel disease. The Company expects to begin its multiple ascending dose study in the second quarter of 2018. The Company previously completed a single ascending dose study for AKB-4924 in human subjects under a Clinical Trial Application (CTA) in Canada.
- Completed a pre-IND meeting with the FDA for ARP-1536, a fully-humanized monoclonal antibody that activates Tie2 by binding the extracellular domain of the vascular endothelial protein tyrosine phosphatase (VE-PTP).

First Quarter 2018 Financial Highlights

As of March 31, 2018, cash and cash equivalents totaled \$13.8 million, compared to \$20.3 million as of December 31, 2017. Total shares outstanding as of March 31, 2018 were 27.1 million.

For the three months ended March 31, 2018, operating expenses totaled \$7.5 million, including \$1.1 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. Net loss attributable to common shareholders for the three months ended March 31, 2018 was \$7.4 million, or \$0.27 per share, compared to a net loss attributable to common shareholders of \$5.9 million, or \$1.06 per share, for the same period in 2017.

Research and development expenses for the three months ended March 31, 2018, increased \$1.8 million, or 79%, compared to the same period in 2017. This increase was the result of increased spending on our lead program AKB-9778, currently in Phase 2b development, partially offset by a decrease in spending on our pipeline programs AKB-4924 and ARP-1536.

General and administrative expenses for the three months ended March 31, 2018, increased \$0.9 million, or 38%, compared to the same period in 2017. This increase was primarily attributable to personnel and related costs, as well as expenses associated with operating as a public company.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases. The Company's lead compound, AKB-9778, is a small molecule activator of the Tie2 pathway and is in clinical development for the treatment of non-proliferative diabetic retinopathy. For more information please visit www.aerpio.com.

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 the intracellular domain of VE-PTP, the most critical negative regulator of Tie2. AKB-9778 has demonstrated the ability to activate 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 activating Tie2.

About Diabetic Retinopathy

Diabetic Retinopathy (DR) is a complication of diabetes caused by damage to blood vessels in the retina. Severity of DR ranges from mild non-proliferative diabetic retinopathy to more advanced proliferative diabetic retinopathy (PDR), the hallmark of which is the development of new abnormal blood vessels.

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 revenues 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, 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 STATEMENTS OF OPERATIONS (In thousands, except per share amounts)

	Three months ended March 31,	
	2018	2017
Operating expenses:		
Research and development	\$4,029	\$2,256
General and administrative	3,448	2,504
Total operating expenses	7,477	4,760
Loss from operations	(7,477)	(4,760)
Interest and other income (expense), net	51	(236)
Net and comprehensive loss	(7,426)	(4,996)
Adjustment of convertible preferred stock	-	(943)
Net loss attributable to common shareholders	\$ (7,426)	\$ (5,939)
Net loss per common share basic and diluted	\$ (0.27)	\$ (1.06)
Weighted average common shares outstanding, basic and diluted	27,046	5,605

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

	March 31, 2018	December 31 2017
Assets		
Current assets:		
Cash and cash equivalents	\$13,764	\$ 20,264
Prepaid R&D contracts	388	313
Other current assets	458	322
Total current assets	14,610	20,899
Furniture and equipment, net	103	107
Deposits	21	21
Total assets	\$ 14,734	\$ 21,028
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$3,623	\$ 3,592
Total current liabilities	3,623	3,592

Stockholders' equity:

 Capital
 127,100
 125,998

 Accumulated deficit
 (115,988)
 (108,563)

 Total stockholders' equity
 11,112
 17,435

 Total liabilities and shareholders' equity
 \$14,734
 \$21,028

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