Aerpio Reports Third Quarter 2019 Financial Results and Provides Business Update

November 7, 2019

CINCINNATI--(BUSINESS WIRE)--Nov. 7, 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 third quarter ended September 30, 2019, and provided a business update.

Recent Developments

As reported on October 21, 2019, the Company announced that its Board of Directors had initiated a process to explore and review a range of strategic alternatives focused on maximizing stockholder value from the Company's clinical assets and cash resources. At that time, the Company also engaged Evercore, Ladenburg Thalmann & Co. Inc., and Duane Nash, M.D, J.D., M.B.A. to act as strategic advisors. The Company cannot guarantee that this process will culminate in a transaction.

In addition, the Company announced a plan to streamline operations in order to preserve capital and cash resources. The Company's management team is now led by Joseph Gardner, Ph.D., the Company's President, and Regina Marek, the Company's Vice President of Finance.

Finally, on September 27, 2019, the Company completed dosing of the first three cohorts of healthy subjects in a Phase 1b clinical trial to evaluate the safety and pharmacokinetics of a topical drop formulation of AKB-9778. The clinical trial is continuing with enrollment of glaucoma patients in the next cohort, with topline results anticipated in the first quarter of 2020.

Third Quarter 2019 Financial Highlights

As of September 30, 2019, cash and cash equivalents totaled $43.4 million. Total shares outstanding, as of September 30, 2019, were 40.6 million.

For the three months ended September 30, 2019, operating expenses totaled $5.0 million, including $0.6 million in non-cash stock compensation expense, compared to $7.6 million, including $0.8 million in non-cash stock compensation expense, for the same period in 2018.

Research and development expenses for the three months ended September 30, 2019, decreased $1.5 million, or 34.6%, compared to the same period in 2018. This decrease was primarily the result of decreased expenses associated with the TIME-2b clinical trial of AKB-9778, offset by spending related to the Phase 1b clinical trial of topical drop formulation of AKB-9778, which commenced during the second quarter of 2019.

General and administrative expenses for the three months ended September 30, 2019, decreased $1.1 million, or 34.1%, compared to the same period in 2018. This decrease was primarily attributable to a decrease in personnel related expenses, legal expenses, non-cash stock compensation expense and other back office related expenses.

Net loss attributable to common shareholders for the three months ended September 30, 2019, was $4.6 million, or $0.11 per share, compared to net income attributable to common shareholders of $11.5 million, or $0.28 per share, for the same period in 2018. Net income in 2018 was attributable to the license revenue of $20.0 million received in June 2018 from Gossamer Bio. $18.8 million was recognized as revenue in the three months ended September 30, 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, through activation of two inhibitors VE-PTP and Ang-2, is found in patients with diabetes and other conditions. The Company's lead compound, AKB-9778, a first-in-class small molecule inhibitor of VE-PTP, is being investigated in an ongoing Phase 1b clinical trial as a topical drop formulation for its therapeutic potential in open-angle glaucoma. In the recently completed Phase 2b study (TIME-2b) AKB-9778 demonstrated the ability to lower proteinuria (as measured by decreasing urinary albumin creatine ratio, UACR) by about 20% replicating a finding in the previous phase 2 study. The decrease in proteinuria suggests that AKB-9778 and our other Tie2 activating drug, ARP-1536, may have the potential to improve kidney function in diabetics potentially delaying progression to kidney dialysis. The Company's second asset, ARP-1536 is a humanized monoclonal antibody observed to activate Tie2 receptors in a dose-dependent manner in preclinical models. Aerpio believes ARP-1536 holds potential as a monthly or biweekly systemic therapy to treat diabetic complications, including diabetic nephropathy. The company's third asset is a bispecific antibody that binds both VEGF and VE-PTP which inhibits VEGF activation and activates Tie2. This bispecific antibody has the potential to be an improved product for treating wAMD and DME via intravitreal injection. Finally, the Company has exclusively out-licensed its fourth asset 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. 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.

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 strategic alternatives review process and the potential transactions that may be identified and explored as a result of that process, the Company's product candidates, including AKB-9778 and ARP-1536, the clinical development plan therefor and the therapeutic potential thereof, 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 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; 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; 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 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 STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
License revenue, and other	$ -	$ 18,822	$ -	$ 20,155
Operating expenses:				
Research and development	2,845	4,346	10,695	12,604
General and administrative	2,161	3,278	8,216	9,866
Restructuring (benefit) expense	(39)	-	876	-
Total operating expenses	4,967	7,624	19,787	22,470
(Loss) income from operations	(4,967)	11,198	(19,787)	(2,315)
Interest and other income	319	339	963	437
Net and comprehensive (loss) income	$ (4,648)	$ 11,537	$ (18,824)	$ (1,878)
Net (loss) income per common share basic and diluted	$ (0.11)	$ 0.28	$ (0.46)	$ (0.06)
Weighted average common shares outstanding				
Basic	40,588	40,528	40,588	31,687
Diluted	40,588	40,962	40,588	31,687

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 43,390	$ 62,614
Prepaid R&D contracts	538	754
Other current assets	876	616
Total current assets	44,804	63,984
Furniture and equipment, net	282	99
Operating lease right-of-use asset	425	
Deposits	41	41
Total assets	$ 45,552	$ 64,124

Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,404	$ 5,457
Current portion of operating lease liability	197	
Total current liabilities	3,601	5,457
Operating lease liability, net of current portion	236	
Total liabilities	3,837	5,457
Stockholders' equity:		
Capital	179,504	177,626
Accumulated deficit	(137,789)	(118,959)
Total stockholders' equity	41,715	58,667
Total liabilities and stockholders' equity	$ 45,552	$ 64,124

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