Aerpio Reports First Quarter 2020 Financial Results and Provides Business Update

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Razuprotafib (formerly known as AKB-9778) Phase 2 Open Angle Glaucoma Trial on Track for Third Quarter Start

CINCINNATI, May 07, 2020 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2020, and provided a business update.

"We continue to be excited about our glaucoma program," said Joseph Gardner, President and Founder. "The statistically significant reductions in intraocular pressure (IOP) together with the favorable tolerability profile observed in the Phase 1b study in combination with standard of care prostaglandin therapy were very encouraging. We look forward to continuing to evaluate razuprotafib in the planned 28-day Phase 2 open angle glaucoma (OAG) study which we currently expect to initiate in the third quarter."

Recent Company Highlights and Upcoming Milestones

- Completed a Phase 1b clinical trial designed to assess the safety of the Company's lead candidate, razuprotafib in the form of topical ocular drops, for patients with OAG and ocular hypertension (OH).
- Presented promising IOP lowering data from the Company's Phase 1b clinical trial of topical ocular formulation of razuprotafib 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 razuprotafib was combined with a prostaglandin appeared comparable to or better than published Phase 3 data for marketed adjuvant therapies.
- Manufactured drug product in preparation for upcoming Phase 2 study of razuprotafib topical drops.

First Quarter 2020 Financial Highlights

As of March 31, 2020, cash and cash equivalents totaled $34.6 million, compared to $38.5 million as of December 31, 2019.

For the three months ended March 31, 2020, operating expenses totaled $4.1 million, a decrease of 53.4%, compared to $8.8 million for the same period in 2019.

Research and development expenses for the three months ended March 31, 2020 decreased $3.8 million, or 67.3%, to $1.8 million from $5.6 million in the three months ended March 31, 2019. This decrease was primarily the result of reduced expenses associated with our clinical programs.

General and administrative expenses for the three months ended March 31, 2020 decreased $1.0 million, or 29.8%, to $2.3 million from $3.3 million in the three months ended March 31, 2019. This decrease was primarily attributable to lower stock compensation expenses, personnel related expenses and general office expenses.

Net loss attributable to common stockholders for the three months ended March 31, 2020 was $3.9 million, or $0.10 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 March 31, 2019.

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, razuprotafib, 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 razuprotafib 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., 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 Razuprotafib

Razuprotafib 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. Razuprotafib 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 razuprotafib in open angle glaucoma and exploring the utility of subcutaneous razuprotafib 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 razuprotafib, 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 razuprotafib 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 impact of the ongoing COVID-19 pandemic on the Company's business operations, including research and development efforts and the ability of the Company to commence, conduct and complete its planned clinical activities; 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, 2019, 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 34,585	$ 38,525
Prepaid research and development contracts	228	311
Other current assets	579	735
Total current assets	35,392	39,571
Furniture and equipment, net	149	164
Operating lease right-of-use assets, net	139	162
Deposits	20	40
Total assets	$ 35,700	$ 39,937
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,548	$ 3,232
Current portion of operating lease liability	107	103
Total current liabilities	2,655	3,335
Operating lease liability, net of current portion	39	67
Total liabilities	2,694	3,402
Stockholders' equity:		
Capital	179,160	178,771
Accumulated deficit	(146,154)	(142,236)
Total stockholders' equity	33,006	36,535
Total liabilities and stockholders' equity	$ 35,700	$ 39,937

AERPIO PHARMACEUTICALS, INC.

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

	Three months ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,829	$ 5,586
General and administrative	2,286	3,255
Total operating expenses	4,115	8,841
Interest and other income	196	348
Net and comprehensive loss	$ (3,919)	$ (8,493)
Net loss per common share basic and diluted	$ (0.10)	$ (0.21)
Weighted average common shares outstanding		
Basic and diluted	40,588	40,588

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Source: Aerpio Pharmaceuticals, Inc.

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