Aerpio Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

March 11, 2021

- *Ended fourth quarter 2020 with $42.6 million in cash and cash equivalents*
- *Aerpio is currently evaluating a range of strategic alternatives focused on maximizing stockholder value from existing clinical and preclinical assets and cash resources*
- *Aerpio discontinued RESCUE trial, prior to completion, due to challenges recruiting and monitoring COVID-19 patients in the current pandemic environment*
- *Aerpio's participation in the I-SPY COVID trial has likewise been discontinued*

CINCINNATI, March 11, 2021 (GLOBE NEWSWIRE) -- Aerpio Pharmaceuticals, Inc. ("Aerpio" or the "Company") (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 in indications in which the Company believes that activation of Tie2 may have therapeutic potential, today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided a business update.

Recent Updates to Company's Business

- In December 2020, Aerpio reported top line results from its Phase 2 trial of razuprotafib in open angle glaucoma and ocular hypertension. While the trial met the primary efficacy endpoint at Day 28 with the twice-daily dosing group, the intraocular pressure ("IOP") decrease was not at a level deemed sufficient to advance to Phase 3 development.

Subsequent Events

- In January 2021, the Company initiated a plan to reduce operating costs and better align its workforce with the needs of its ongoing business. The plan reduces its current workforce by 7 employees, representing approximately 58% of the Company's workforce. The Company estimates it will incur a one-time employee-related severance charge of approximately $1.2 million during the first quarter of 2021 with the majority of severance-related payments being paid by the end of fiscal 2021.
- In February 2021, Aerpio discontinued its RESCUE trial for the prevention and treatment of acute respiratory distress syndrome ("ARDS") in adult patients with moderate to severe COVID-19 sponsored by the Medical Technology Enterprise Organization ("MTEC") after the first 31 patients based on challenges associated with recruiting and monitoring patients in the current pandemic environment. There were no apparent safety signals associated with dosing COVID-19 patients with razuprotafib. The Company expects to report top-line data from the enrolled patients during the second quarter of 2021.
- In March 2021, Aerpio and Quantum Leap Health Collaborative disclosed that the razuprotafib treatment arm has been discontinued from the I-SPY COVID-19 trial based on the complexity of monitoring patients during a pandemic surge in patients admitted to the intensive care unit. There were no apparent safety signals associated with razuprotafib.

The Company continues to explore strategic options for partnering its programs, as well as the potential for an acquisition, company sale, merger, business combination, asset sale, in-license, out-license or other strategic transaction. Ladenburg Thalmann & Co. Inc. is acting as Aerpio's financial advisor with respect to the strategic review process. There can be no assurance that this exploration of strategic alternatives will result in the Company entering or completing any transaction. Aerpio does not intend to make any further disclosures regarding the strategic review process unless and until specific actions are approved.

Fourth Quarter and Full Year 2020 Financial Highlights

As of December 31, 2020, cash and cash equivalents totaled $42.6 million, compared to $38.5 million as of December 31, 2019. Weighted average number of shares outstanding as of December 31, 2020 was approximately 42.6 million.

For the three months ended December 31, 2020, operating expenses totaled $5.6 million, an increase of 21.0% compared to $4.7 million for the same period in 2019. Operating expenses for the full year ended December 31, 2020, was $21.4 million compared to $24.4 million for the full year ended December 31, 2019.

Research and development expenses for the three months ended December 31, 2020, increased approximately $1.1 million, or 51.8%, to $3.2 million from $2.1 million in the three months ended December 31, 2019. This increase was primarily the result of increased expenses associated with the Phase 2 clinical trials of razuprotafib. Research and development expenses for the full year ended December 31, 2020, decreased approximately $0.2 million, or 1.8% to $12.6 million from $12.8 million in the full year ended December 31, 2019. This decrease was primarily the result of a slight decrease in expenses associated with our clinical programs.

General and administrative expenses for the three months ended December 31, 2020, increased approximately $0.9 million, or 56.1%, to $2.4 million from $1.5 million, in the three months ended December 31, 2019. This increase was primarily attributable to stock-based compensation expense offset by lower personnel related expenses. General and administrative expenses for the full year ended December 31, 2020, decreased approximately $1.0 million, or 10.2% to $8.8 million from $9.8 million in the full year ended December 31, 2019. This decrease was primarily the result of decreased employee-related expenses and office expenses offset by increase in consulting and insurance expenses.

Net loss attributable to common stockholders for the three months ended December 31, 2020, was $4.7 million, or $0.10 per share, compared to $4.4 million, or $0.11 per share, for the same period in 2019. Net loss attributable to common stockholders for the full year ended December 31, 2020, was $4.3 million, or $0.10 per share compared to a net loss attributable to common stockholders of $23.3 million, or $0.57 per share, for the full year ended December 31, 2019.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 for indications in which the Company believes that activation of Tie2 may have therapeutic potential. The Company's lead compound, razuprotafib (formerly AKB-9778), a first-in-class small molecule inhibitor of vascular endothelial protein tyrosine phosphatase ("VE-PTP"). 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. (Nasdaq: GOSS). In January 2021, the Company announced that it 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. 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 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 razuprotafib, ARP-1536 and the bispecific antibody asset, the clinical development plan therefor, and the therapeutic potential thereof, the Company's plans and expectations with respect to razuprotafib and the development therefor and therapeutic potential thereof in addressing COVID-19 and ARDS related thereto and the intended benefits from the Company's collaboration with Gossamer Bio for GB004, including the continued development of GB004 and the milestone and royalty payments related to the collaboration. 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 continued development of GB004 and maintaining and deriving the intended benefits of the Company's collaboration with Gossamer Bio; ability to continue to develop razuprotafib or other product candidates, including in indications related to COVID-19; our review and evaluation of strategic plans for our razuprotafib glaucoma program; 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; obtaining any necessary regulatory clearances in order to commence and conduct planned or future 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; 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, 2020, 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.

Contacts

Investors & Media:
Aerpio Pharmaceuticals, Inc.

Gina Marek
VP Finance
gmarek@aerpio.com

Or

Investors:
Irina Koffler
LifeSci Advisors
ikoffler@lifesciadvisors.com

Source: Aerpio Pharmaceuticals, Inc.

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 42,605	$ 38,525
Prepaid research and development contracts	510	311
Other current assets	1,604	735
Total current assets	44,719	39,571
Furniture and equipment, net	122	164
Operating lease right-of-use assets, net	64	162
Deposits	20	40
Total assets	$ 44,925	$ 39,937
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,800	$ 3,232
Current portion of operating lease liability	67	103
Total current liabilities	1,867	3,335
Operating lease liability, net of current portion	-	67
Total liabilities	1,867	3,402
Stockholders' equity:		
Capital	189,609	178,771
Accumulated deficit	(146,551)	(142,236)
Total stockholders' equity	43,058	36,535
Total liabilities and stockholders' equity	$ 44,925	$ 39,937

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

	Three months ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
License revenue	$ -	$ -	$ 15,000	$ -
Operating expenses:				
Research and development	3,231	2,129	12,595	12,824
General and administrative	2,405	1,541	8,762	9,756
Restructuring expense	-	987	-	1,864
Total operating expenses	5,636	4,657	21,357	24,444
Loss from operations	(5,636)	(4,657)	(6,357)	(24,444)
Interest and other income	919	211	2,042	1,173
Net and comprehensive loss	$ (4,717)	$ (4,446)	$ (4,315)	(23,271)
Net loss per common share basic and diluted	$ (0.10)	$ (0.11)	$ (0.10)	$ (0.57)
Weighted average common shares outstanding				
Basic and diluted	47,137	40,588	42,624	40,588

Source: Aerpio Pharmaceuticals, Inc.