Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces 2020 Fourth Quarter and Year-End Financial Results and Business Update

LOS GATOS, Calif., March 30, 2021 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies to treat life-threatening infections, today reported financial and corporate results for the fourth quarter ended December 31, 2020.

Fourth Quarter Highlights and Recent Developments

- Announced positive preclinical efficacy data for AR-711, a potential inhaled, self-administered, at-home monoclonal antibody treatment ("mAb") for non-hospitalized mild-to-moderate COVID-19 patients. A clinical Phase 1/2 study is expected to be launched in 2H 2021.
- Received concurrence from the U.S. Food and Drug Administration ("FDA") to streamline AR-501's Phase 2 clinical trial design and to expand the originally planned Phase 2a protocol design into a Phase 2a/2b study for treating chronic lung infections in patients with cystic fibrosis (CF). Enrollment completion is expected in late 2021.
- Continued enrolling global Phase 3 clinical trial of AR-301 in patients with ventilator associated pneumonia (VAP) including patients who presented with *S. aureus* VAP as a secondary infection to COVID-19. Interim futility analysis is expected in 2H 2021 and top-line data expected in 1H 2022.
- Entered into a ΛPEX™ out-licensing and product discovery agreement with Kermode Biotechnologies, Inc. on vaccines and mAbs for zoonotic viruses, which are animal viruses that have the ability to infect humans.
- Licensed the CRISPR gene editing technology from the Broad Institute of MIT and Harvard. CRISPR is a key component of the APEX™ mAb discovery and production platform technology.
- Executed a Registered Direct offering with gross proceeds of approximately $8.5 million in the fourth quarter and approximately $7.0 million in March 2021.

"During the fourth quarter and over the recent months, we achieved multiple important milestones that impact our clinical and corporate profile, highlighted by the addition of an inhaled at-home COVID-19 treatment (AR-712) to our portfolio of product candidates and entering into an ΛPEX™ out-licensing and product discovery agreement with Kermode Biotechnologies for zoonotic viruses," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Additionally, we reached concurrence with the FDA to streamline and thus expedite the clinical and regulatory process for AR-501's Phase 2 program in cystic fibrosis, and bolstered our balance sheet with the $15.5 million financing. These important achievements have helped position us for continued growth as we head into 2021."

COVID-19 Program Update

AR-712: During the quarter, Aridis announced the development of a highly potent fully human mAb against SARS-CoV-2 virus. AR-712 is a cocktail of two mAbs, AR-711 and AR-713, designed to lower the barrier to treatment coverage of non-hospitalized COVID-19 patients by using a convenient, self-administered inhaled dosage presentation. The two mAbs that comprise AR-712 were discovered from convalescent COVID-19 patients and target the receptor-binding domain (RBD) region of the spike protein of the original SARS-CoV2 virus and its newly emerging variants including the currently prevalent strain 'E484K' associated with the South Africa, Brazil, and Japan variants.

In an animal challenge study with golden Syrian hamsters, inhaled AR-711 successfully eliminated all detectable SARS-CoV-2 virus at substantially lower doses than parenterally administered (injected) COVID-19 mAb. The AR-712 mAbs are engineered to be long-acting in blood for up to six to twelve months and are stabilized using a proprietary formulation designed to protect the mAbs from the physical stresses imparted by commercial nebulizer delivery devices on protein drugs. The potency of AR-712 and its direct delivery to the lungs by inhaled administration may facilitate significant dose sparing not achievable by parenteral administration. A proprietary formulation enables AR-712 to be deliverable using a variety of commercially available nebulizers that can be self-administered on an outpatient basis, thus lowering the barrier to COVID-19 therapeutic treatment. Clinical trials for AR-712 are expected to commence 2H 2021.

AR-701: During the quarter, Aridis continued to characterize this cocktail of fully human mAbs discovered from its in-house ΛPEX™ mAb discovery platform that is directed at multiple envelope proteins of the SARS-CoV-2 virus. AR-701 is intended to treat hospitalized, moderate to severe patients, which complements AR-712's focus on milder non-hospitalized patients.

Clinical Program Update

AR-301: AR-301 is being evaluated in Phase 3 clinical study as an adjunctive treatment to standard of care antibiotics in *S. aureus* infected ventilator associated pneumonia (VAP) patients. Thus far, the pace of the trial has continued to be impacted by the protracted COVID-19 pandemic. The Phase 3 interim futility analysis from the ongoing pivotal trial is now expected to be reported in 2H 2021 and top line data by 1H 2022. It's important to note that COVID-19 patients on prolonged mechanical ventilation in the intensive care unit (ICU) are prone to secondary infections (also called 'superinfections') by opportunistic pathogens such as bacteria. Superinfection is a reported complication in COVID-19 patients, which exacerbates morbidity and the rate of mortality. The AR-301 Phase 3 study allows for the enrollment of patients with baseline characteristics which are inclusive of certain COVID-19 patients. While AR-301 is not an agent to treat SARS-CoV-2 virus itself, it can potentially reduce the morbidity associated with secondary *S. aureus* pneumonia, which is a coronavirus complication and a contributing cause of death in such patients.

The trial, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 160 clinical centers in 22 countries. Participating clinical centers that are activated continue to follow standard stringent clinical protocols and procedures for critically ill VAP patients, as is standard in the U.S. and Europe. The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human monoclonal antibody to treat acute pneumonia in the intensive care unit setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

AR-501: During the quarter, the Company announced an agreement with the FDA to simplify AR-501's Phase 2 trial design for the treatment of chronic lung infections associated with cystic fibrosis (CF). After reporting (June 2020) positive Phase 1 safety data in healthy adults who were exposed to a single ascending dose (SAD) or a multiple ascending dose (MAD) regimen, Aridis proposed, and the FDA has now agreed, to streamline AR-501's forthcoming Phase 2a clinical trial in CF patients by removing the SAD and only conducting a MAD regimen. The FDA also concurred with the Company's proposal to expand the originally planned Phase 2a protocol design into a Phase 2a/2b study. This Phase 2a/2b design will enable seamless and efficient advancement of the study from Phase 2a into Phase 2b using the same clinical study protocol. The data from the Phase 2a will inform the dose selection and sample size expansion to achieve statistical significance in efficacy in Phase 2b.

AR-501 is being developed in collaboration with the CF Foundation and has been granted Orphan Drug Designation (ODD), Fast Track and Qualified Infectious Disease Product (QIDP) designations by the FDA. In addition, the European Medicines Agency (EMA) granted ODD to AR-501. The original Phase 1/2a clinical trial was a randomized, double-blinded, placebo-controlled SAD and MAD trial investigating the safety and PK of inhaled AR-501 in healthy volunteers and cystic fibrosis patients with chronic bacterial lung infections. Details of the original Phase 1/2a clinical trial can be viewed on www.clinicaltrials.gov using identifier NCT03669614. The new Phase 2a/b study design will be available on clinicaltrials.gov within the next quarter.

Corporate Update

A key development was the closing of an $8.5 million financing which occurred on October 14th. The proceeds from this registered direct offering and concurrent private placement, strengthens the Company's balance sheet during the fourth quarter to prioritize the continued advancement of AR-301's Phase 3 VAP clinical trial, while allocating the requisite resources to AR-501's Phase 2b cystic fibrosis clinical trial, and the ongoing development of novel COVID-19 therapies such as AR-701 and AR-711.

Fiscal 2020 Fourth Quarter Results:

- **Cash**: Total cash and cash equivalents as of December 31, 2020 was $8.2 million. The Company completed a registered direct financing in March 2021 and received gross proceeds of approximately $7.0 million.
- **Revenues:** Revenue was approximately $1 million for both periods ended December 31, 2020 and 2019. There was no revenue for both quarters ended December 31, 2020 and 2019.
- **Research and Development Expenses:** Research and development expenses decreased by approximately $7.1 million from $24.1 million for the year ended December 31, 2019 to $17.0 million for the year ended December 31, 2020. The year over year decrease was primarily due to the following: a decrease in spending on clinical trial activities and drug manufacturing expenses for the Phase 2 study of our AR-105 program that was terminated during 2019; a decrease in drug manufacturing expenses for the Phase 3 study of our AR-301 program; a decrease in spending on clinical trial activities for the Phase 1/2a study of our AR-501 program because the Phase 1 portion of the study ended in the second quarter of 2020; a decrease in spending on other research and development activities; and a decrease in personnel, consulting and other related costs. These decreases were partially offset by an increase in spending on research and development activities for our COVID-19 program.
- There was no material difference in research and development expenses for the quarter ended December 31, 2020 when compared to the same period in 2019.
- **General and Administrative Expenses:** General and administrative expenses increased by approximately $419,000 from $6.0 million for the year ended December 31, 2019 to $6.4 million for the

year ended December 31, 2020 due primarily to increases in directors' and officers' related liabilities insurance expense, professional service fees, and rent expense due to the Company entering into a new facility lease during the fourth quarter of 2020. These increases were partially offset by a decrease in patent related fees and Delaware franchise taxes. General and administrative expenses incurred in the quarter ended December 31, 2020 were approximately $1.6 million, an increase of approximately $204,000 over the same period in 2019 which was due primarily to increases in professional service fees, personnel related expenses, including stock-based compensation, and rent expense due to the Company entering into a new facility lease during the fourth quarter of 2020, partially offset by a decrease in Delaware franchise taxes.

- **Interest Income, net:** Interest income, net decreased by approximately $280,000 from $357,000 for the year ended December 31, 2019 to $77,000 for the year ended December 31, 2020. Interest income, net for the quarter ended December 31, 2020 decreased by approximately $82,000 over the same period in 2019. These decreases are primarily due to lower interest rates and a lower average cash balance during 2020 as compared to 2019.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment decreased by approximately $942,000 from approximately $951,000 for the year ended December 31, 2019 to $9,000 for the year ended December 31, 2020 as our share of loss from our minority interest in the JV Agreement with Shenzhen Hepalink Pharmaceutical Group Co., Ltd., calculated under the equity method was limited to the reduction of the net book value of the investment to zero as of March 31, 2020. Loss from equity method investment decreased by $41,000 for the quarter ended December 31, 2020 when compared to the same period in 2019 which was due to there being no share of losses from our equity method investment recorded in the fourth quarter of 2020 as the net book value of the investment has been zero since March 31, 2020.
- **Net Loss:** The net loss for the year ended December 31, 2020 was $22.3 million, or $2.44 net loss per share, compared to a net loss of $29.7 million, or $3.51 net loss per share per share, for the year ended December 31, 2019. The net loss for the quarter ended December 31, 2020 was $5.8 million, or $0.59 net loss per share, compared to a net loss of approximately $5.6 million, or $0.63 net loss per share, for the quarter ended December 31, 2019. The weighted average common shares outstanding was approximately 9.2 million and approximately 8.5 million for the year ended 2020 and 2019, respectively.

About Aridis Pharmaceuticals, Inc.
Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as add-on treatments to standard-of-care antibiotics. The Company is utilizing its proprietary ΛPEX™ and MabIgX® technology platforms to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection, and to rapidly manufacture monoclonal antibody (mAbs) for therapeutic treatment of critical infections. These mAbs are already of human origin and functionally optimized for high potency by the donor's immune system; hence, they technically do not require genetic engineering or further optimization to achieve full functionality.

The Company has generated multiple clinical stage mAbs targeting bacteria that cause life-threatening infections such as ventilator associated pneumonia (VAP) and hospital acquired pneumonia (HAP), in addition to preclinical stage antibacterial and antiviral mAbs. The use of mAbs as anti-infective treatments represents an innovative therapeutic approach that harnesses the human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care which is broad spectrum antibiotics. Such deficiencies include, but are not limited to, increasing drug resistance, short duration of efficacy, disruption of the normal flora of the human microbiome and lack of differentiation among current treatments. The mAb portfolio is complemented by a non-antibiotic novel mechanism small molecule anti-infective candidate being developed to treat lung infections in cystic fibrosis patients. The Company's pipeline is highlighted below:

Aridis' Pipeline
AR-301 (VAP). AR-301 is a fully human IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *Staphylococcus aureus* (*S. aureus)* alpha-toxin in VAP patients.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* (*P. aeruginosa)* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide.

AR-501 (cystic fibrosis). AR-501 is an inhaled formulation of gallium citrate with broad-spectrum anti-infective activity being developed to treat chronic lung infections in cystic fibrosis patients. This program is currently in a Phase 2a clinical study in healthy volunteers and CF patients.

AR-401 (blood stream infections). AR-401 is a fully human mAb preclinical program aimed at treating infections caused by gram-negative *Acinetobacter baumannii*.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients

that are directed at multiple envelope proteins of the SARS-CoV-2 virus.

AR-712 (COVID-19). AR-712 is cocktail of two fully human IgG1 mAbs, AR-711 and AR-713, that are directed against the receptor binding domain of the SARS-CoV 2 virus. AR-712 is being developed to treat non-hospitalized mild to moderate COVID-19 patients by inhalation using a nebulizer.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb directed against the F-protein of diverse clinical isolates of respiratory syncytial virus (RSV). This program is licensed exclusively to the Serum Institute of India.

For additional information on Aridis Pharmaceuticals, please visit https://aridispharma.com/.

Forward-Looking Statements
Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Aridis' expectations, strategy, plans or intentions. These forward-looking statements are based on Aridis' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the need for additional financing, the timing of regulatory submissions, Aridis' ability to obtain and maintain regulatory approval of its existing product candidates and any other product candidates it may develop, approvals for clinical trials may be delayed or withheld by regulatory agencies, risks relating to the timing and costs of clinical trials, risks associated with obtaining funding from third parties, management and employee operations and execution risks, loss of key personnel, competition, risks related to market acceptance of products, intellectual property risks, risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses, risks associated with the uncertainty of future financial results, Aridis' ability to attract collaborators and partners and risks associated with Aridis' reliance on third party organizations. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, market conditions and the factors described under the caption "Risk Factors" in Aridis' 10-K for the year ended December 31, 2020 and Aridis' other filings made with the Securities and Exchange Commission. Forward-looking statements included herein are made as of the date hereof, and Aridis does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Aridis Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 8,232	$ 20,897
Other current and noncurrent assets	6,885	7,070
Total Assets	$ 15,117	$ 27,967
Total Liabilities	$ 23,798	$ 24,331
Total stockholders' equity (deficit)	(8,681)	3,636
Total liabilities and stockholders' equity (deficit)	$ 15,117	$ 27,967

Aridis Pharmaceuticals, Inc.

Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended	Twelve Months Ended

	December 31,		December 31,	
	2020	2019	2020	2019
	(unaudited)			
Revenue	$ —	$ —	$ 1,000	$ 1,022
Operating Expenses*				
Research and development	4,231	4,301	16,956	24,083
General and administrative	1,592	1,388	6,445	6,026
Total operating expenses	5,823	5,689	23,401	30,109
Loss from operations	(5,823)	(5,689)	(22,401)	(29,087)
Other income (expense)				
Interest income, net	—	82	77	357
Share of loss from equity method investment	—	(41)	(9)	(951)
Net loss	$ (5,823)	$ (5,648)	$ (22,333)	$ (29,681)
Weighted-average common shares outstanding, basic and diluted	9,903,459	8,914,563	9,168,744	8,458,277
Net loss per share, basic and diluted	$ (0.59)	$ (0.63)	$ (2.44)	$ (3.51)
*Includes stock based-compensation as follows				
Research and development	$ 159	$ 123	$ 590	$ 662
General and administrative	407	366	1,538	1,348
	$ 566	$ 489	$ 2,128	$ 2,010

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