Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces First Quarter 2021 Results

LOS GATOS, Calif., May 11, 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 first quarter ended March 31, 2021.

First Quarter Highlights

- Announced the addition of a second inhaled monoclonal antibody ("mAb") to neutralize newly emerging COVID-19 mutated variant to form a cocktail of two mAbs. The expansion of COVID virus strain coverage, combined with the product's self-administered, at-home treatment modality, further differentiates the company's AR-712 COVID treatment offering. A clinical Phase 1/2 study is expected to be launched in 2H 2021.
- Announced the preclinical development services support of the company's COVID mAb program from NIAID and the Coronavirus Immunotherapy Consortium (CoVIC).
- Licensed the CRISPR gene editing technology from the Broad Institute of MIT and Harvard. CRISPR is a component of the ΛPEX™ mAb discovery and production platform technology.
- 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 and potentially lead to a viral pandemic.
- 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.
- Executed a registered direct offering with gross proceeds of approximately $8.5 million in the fourth quarter of 2020 and approximately $7.0 million in March 2021.

"As the pandemic has raged on this past year, with the virus evolving into more transmissible and lethal variants, we have been able to adapt our mAb offering to expand strain coverage to all key SARS-COV-2 variants," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "We also continued to optimize our versatile ΛPEX mAb discovery platform technology and entered into a partnership to develop mAbs and vaccines for viruses with pandemic potential", continued Truong. "We expect to maintain a high pace of execution and to position the company for an outstanding 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. Our antibody also neutralizes the California strain, which harbors the L452R mutation.

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 a 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 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 initiated the Phase 2a study to evaluate the safety, pharmacokinetic, and preliminary efficacy evaluation in cystic fibrosis (CF) patients. The Phase 2a is set to enroll 42 cystic fibrosis adult patients and is expected to complete enrollment by the end of 2021.

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.

Corporate Update

A key development was the closing of a $7.0 million financing which occurred in March 2021. The proceeds from this registered direct offering strengthened the Company's balance sheet during the first quarter to support 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-712 and AR-401.

Fiscal 2021 First Quarter Results:

- **Cash**: Total cash and cash equivalents as of March 31, 2021 were $10.5 million. The Company completed a registered direct financing in March 2021 and received gross proceeds of approximately $7.0 million.

- **Revenues:** Revenue was zero for the quarters ended March 31, 2021 and 2020.

- **Research and Development Expenses:** Research and development expenses increased by approximately $38,000 from approximately $4.9 million for the quarter ended March 31, 2020 to approximately $5.0 million for the quarter ended March 31, 2021. The quarter over quarter increase was primarily due to an increase in spending on other research and development activities, an increase in spending on research and development activities for our COVID-19 programs and an increase in personnel, consulting and other related costs. These were partially offset by a decrease in spending on clinical trial activities and drug manufacturing expenses for the Phase 3 study of our AR-301 program and a decrease in spending on clinical trial activities and drug manufacturing expenses as we continue to wind-down the Phase 2 study of our AR-105 program that was terminated during 2019.

- **General and Administrative Expenses:** General and administrative expenses increased by approximately $305,000 from approximately $1.6 million for the quarter ended March 31, 2020 to approximately $1.9 million for the quarter ended March 31, 2021 which was due primarily to increases in personnel related expenses, including stock-based compensation, professional service fees, and Delaware franchise taxes.

- **Interest Income, net:** Interest income, net decreased by approximately $60,000 from approximately $61,000 for the quarter ended March 31, 2020 to approximately $1,000 for the quarter ended March 31, 2021 which is due primarily to lower average cash balances during the first quarter in 2021 as compared to the same period in 2020.

- **Other Income:** Other income increased by approximately $7,000 from zero for the quarter ended March 31, 2020 to approximately $7,000 for the quarter ended March 31, 2021 which related to sublease income from a sublease agreement we entered into with a tenant on March 1, 2021 to sublet a small portion of our

Los Gatos facility. There was no sublease agreement or related income during the quarter ended March 31, 2020.

- **Share of Loss from Equity Method Investment:** Loss from equity method investment decreased by approximately $9,000 from approximately $9,000 for the quarter ended March 31, 2020 to zero for the quarter ended March 31, 2021 which was due to there being no share of losses from our equity method investment recorded in the first quarter of 2021 as the net book value of the investment has been zero since March 31, 2020.

- **Net Loss:** The net loss available to common stockholders for the quarter ended March 31, 2021 was approximately $7.9 million, or $0.77 net loss per share, compared to a net loss available to common stockholders of approximately $6.5 million, or $0.73 net loss per share, for the quarter ended March 31, 2020. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was approximately 10.2 million and approximately 8.9 million for the first quarter of 2021 and 2020, respectively.

About Aridis Pharmaceuticals, Inc.
Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as first-line treatments to combat antimicrobial resistance (AMR) and viral pandemics. 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 by the natural human immune system for high potency. Hence, they are already fit-for-purpose and do not require further engineering 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)

	March 31, 2021	December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 10,472	$ 8,232
Other current and noncurrent assets	7,097	6,885
Total Assets	$ 17,569	$ 15,117
Total Liabilities	$ 26,124	$ 23,798
Total stockholders' deficit	(8,555)	(8,681)
Total liabilities and stockholders' deficit	$ 17,569	$ 15,117

Aridis Pharmaceuticals, Inc.

Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Revenue	$ —	$ —
Operating Expenses*		
Research and development	4,955	4,917
General and administrative	1,944	1,639

Total operating expenses	6,899	6,556
Loss from operations	(6,899)	(6,556)
Other income (expense)		
Interest income, net	1	61
Other income	7	—
Share of loss from equity method investment	—	(9)
Net loss	$ (6,891)	$ (6,504)
Deemed dividends	$ (986)	$ —
Net loss available to common stockholders	$ (7,877)	$ (6,504)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	10,230,043	8,919,393
Net loss per share available to common stockholders, basic and diluted	$ (0.77)	$ (0.73)
*Includes stock based-compensation as follows		
Research and development	$ 160	$ 145
General and administrative	407	332
	$ 567	$ 477

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