Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces 2021 Fourth Quarter and Year-End Financial Results and Business Update

Awarded funding from the Gates Foundation to support development of inhaled formulation technology to deliver cost-effective monoclonal antibodies against influenza and COVID-19

LOS GATOS, Calif., March 31, 2022 /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 its fourth quarter and year ended December 31, 2021.

Fourth Quarter Highlights

- Continued enrollment in the Company's Phase 2a study of AR-501 targeting cystic fibrosis (CF), conducted in collaboration with the funding support from the CF Foundation. Aridis is on track to report top-line data from this CF study in mid-2022.
- Continued enrollment in the Company's Phase 3 study evaluating AR-301 for the treatment of Ventilator Associated Pneumonia (VAP). Aridis is on track to report top-line data in the second half of 2022.
- The Company is on track to initiate the Phase 3 trial of AR-320 for the prevention of VAP in mid-2022 following regulatory feedback on the clinical development plans and Phase 3 study design received from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). Clarity on the regulatory pathway to the registrational Phase 3 trial and licensure has been achieved. The Phase 3 SAATELLITE-2 study will be conducted in collaboration with the COMBACTE-Net consortium of HAP/VAP experts, funded up to 25 million Euros by the Innovative Medicines Initiative (IMI) program of the European Commission.
- Reported preclinical data demonstrating that AR-701, the Company's first fully human monoclonal antibody (mAb) cocktail, is broadly reactive against the Omicron and other SARS-CoV-2 (COVID-19) variants, SARS (Severe Acute Respiratory Syndrome), MERS (Middle East Respiratory Syndrome Coronavirus), and multiple seasonal ('common cold') human coronavirus strains.
- In January 2022, Aridis announced that it had received a $1.9 million grant from the Bill and Melinda Gates Foundation (Gates Foundation) to evaluate the application of the Company's inhaled formulation technology to deliver cost-effective monoclonal antibodies (mAbs) against influenza and SARS-CoV-2 to people in low- and middle-income countries.
- Signed loan agreement for $10 million in non-dilutive financing with Streeterville Capital. Received first $5 million payment in November 2021 and the second $5 million payment in February 2022.

"I am proud of our team's work in 2021 as we strengthened our foundation and advanced key development programs," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "2022 will be a pivotal year for Aridis as we achieve important clinical milestones, including data readout from our AR-501 Phase 2a and AR-301 Phase 3 studies as well as the initiation of the AR-320 registrational Phase 3 study, and the anticipated launch of the first-in-human clinical study of AR-701. We look forward to sharing further updates on the progress of these programs in the coming months as we continue to build our leadership in the respiratory health space."

Clinical Program Update

AR-301 (tosatoxumab): AR-301 is being evaluated in a Phase 3 clinical study as an adjunctive treatment to standard of care antibiotics in *S. aureus* VAP patients. The ongoing AR-301 Phase 3 study remains blinded, and the independent Data Monitoring Committee with access to unblinded data continues to monitor study subjects for safety and has not expressed any safety concerns. The Company observed modest improvement in enrollment in recent months despite the continued pandemic. However, because a significant number of participating clinical sites in the study are in Eastern Europe, the escalating Ukraine-Russia conflict is expected to negatively impact enrollment. At the present time, the company anticipates reporting top-line data in the second half of 2022.

The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human mAb to treat acute pneumonia in the ICU setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

AR-320 (suvratoxumab): The Company licensed this Phase 3-ready asset from AstraZeneca in July 2021. A multinational, randomized, double-blind, placebo-controlled Phase 2 study (n=196 patients) showed that mechanically ventilated ICU patients colonized with *S. aureus* who were treated with suvratoxumab, a fully human mAb, demonstrated a relative risk reduction in onset of pneumonia by 32% in the overall intent-to-treat (ITT) study population, and by a statistically significant 47% in the under 65-year-old population, which is the target population in the planned Phase 3 study. This statistically significant relative risk reduction in the target population was also associated with a substantial reduction in the duration of care needed in the ICU and hospital. The Company completed successful discussions with the EMA via the Scientific Advisory meeting and the FDA via an End-of-Phase 2 meeting, including obtaining agreement on the planned Phase 3 study serving as a single pivotal trial. The regulatory feedback from these agencies is incorporated in the Company's clinical study design. The Company expects to launch its Phase 3 SAATELLITE-2 study of AR-320 in the mid-2022 in collaboration with the public-private COMBACTE-Net consortium of HAP/VAP experts, funded by the Innovative Medicines Initiative (IMI) program of the European Commission in the amount of up to 25 million Euros.

AR-501 (gallium citrate): The Company initiated its Phase 2a study to evaluate the safety, pharmacokinetic (PK), and preliminary efficacy in cystic fibrosis (CF) patients in the first quarter of 2021. The Phase 2a study is actively enrolling patients with a goal of delivering full data readout in mid-2022. 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 Phase 1/2a clinical trial underway is a randomized, double-blind, placebo-controlled trial, utilizing single- and multiple-ascending dose and dose-ranging strategies, investigating the safety and PK of inhaled AR-501 in healthy volunteers and CF patients with chronic bacterial lung infections. Details of the Phase 1/2a clinical trial can be viewed on https://www.clinicaltrials.gov using identifier NCT03669614.

AR-701: AR-701 is a cocktail of two fully human immunoglobulin G1 (IgG1) mAbs discovered from screening the antibody secreting B-cells of convalescent SARS-CoV-2 infected (COVID-19) patients. Each mAb of the AR-701 cocktail neutralizes coronaviruses using a distinct mechanism of action, namely inhibition of viral fusion and entry into human cells (AR-703) or blockage of viral binding to the human 'ACE2' receptor (AR-720). The AR-701 mAbs are engineered to be half-life extended and potentially active for 6-12 months in the blood. AR-701 is being developed as a long-acting intramuscular prophylactic to prevent COVID-19 infections, as well as a self-administered inhaled formulation for the treatment of COVID-19 patients who are not yet hospitalized. In February 2022, Aridis reported that both of its fully human mAbs in the AR-701 cocktail neutralized the SARS-CoV-2 Omicron variant. Moreover, both mAbs conferred strong protection against Omicron infected animals when given either parenterally or by intranasal administration. The performance of the AR-701 cocktail is published in Biorxiv [see https://www.biorxiv.org/content/10.1101/2022.03.05.483133v1]. We expect to initiate a Phase 1 clinical study in 2H2022.

Fiscal 2021 Financial Results:

- **Cash**: Total cash, cash equivalents and restricted cash as of December 31, 2021, were approximately $20.0 million.
- **Revenues:** Grant and licensing revenue increased to approximately $1.5 million for the year ended December 31, 2021 primarily due to the recognition of revenue from grants from the Cystic Fibrosis Foundation (CFF) and the Gates Foundation as well as from Kermode, an Apex technology licensee. Grant and licensing revenue earned during the year ended December 31, 2020 was approximately $1.0 million, all from

CFF. Grant and licensing revenue was approximately $0.6 million and $0 for the three months ended December 31, 2021 and 2020, respectively.

- **Research and Development Expenses:** Research and development expenses increased by approximately $21.0 million to $38.0 million for year ended December 31, 2021 from $17.0 million for the year ended December 31, 2020. The increase was due primarily to: an increase of approximately $11.5 million to in-license AR-320 rights from Medimmune; an increase of approximately $6.6 million for AR-320 drug manufacturing and clinical trial preparation costs; an increase of approximately $0.7 million for costs associated with the development of AR-701; an increase of approximately $0.5 million for the continuing conduct of the Phase 2a clinical trial evaluating AR-501 for the treatment of Cystic Fibrosis and an increase of approximately $0.6 million in personnel, consulting and other related costs.
  Research and development expenses increased by approximately $4.4 million in the quarter ended December 31, 2021 to $8.6 million from $4.2 million in the same quarter in 2020. This is primarily due to increases in drug manufacturing for our AR-320 trial ($2.8 million), spending on the Gates Foundation funded project ($0.5 million) and spending on personnel, consulting and other related costs ($0.4 million).
- **General and Administrative Expenses:** General and administrative expenses increased by approximately $0.9 million to $7.3 million for the year ended December 31, 2021 from $6.4 million for the year ended December 31, 2020. The increase was due primarily to increases in professional service fees, franchise tax and recruitment expense to attract talent. General and administrative expenses increased in Q4 2021 to $2.0 million from $1.6 million in Q4 2020 primarily due to increases in consulting, legal fees, insurance and recruitment offset by lower accounting, rent and repairs expense.
- **Interest Income (Expense) net:** Net interest expense, increased by approximately $322,000 to approximately $245,000 for the year ended December 31, 2021 from approximately $77,000 net interest income for the year ended December 31, 2020. The increased expense was primarily due to our debt servicing in 2021.
- **Share of Loss in Equity Method Investment.** Loss from our share of equity method investment in Shenzhen Arimab Biopharmaceuticals Co., Ltd. decreased by approximately $9,000 to zero for the year ended December 31, 2021. The loss was $9,000 for the year ended December 31, 2020. Our share of loss from our minority interest 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.
- **Other Income:** Other income in the year ended December 31, 2021, increased by approximately $796,000 from zero during the year ended December 31, 2020, primarily due to forgiveness of the $722,000 Paycheck Protection Program loan by the U.S. Small Business Administration. Additionally, other income from a sublease agreement we entered into with a tenant in March 2021 to sublet a small portion of our Los Gatos facility increased by approximately $74,000 during the year ended December 31, 2021, from zero for the year ended December 31, 2020. Other income increased by approximately $22,000 in Q4 2021. There was no sublease agreement or related income during the three months ended December 30, 2020.
- **Net Loss:** The net loss available to common stockholders for the year ended December 31, 2021, was approximately $47.3 million, or $3.85 net loss per share, compared to a net loss available to common stockholders of approximately $22.3 million, or $2.44 net loss per share, for the year ended December 31, 2020. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was 12,291,600 million and 9,168,744 million for the years ended December 31 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 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-320 (nosocomial pneumonia). AR-320 is a fully human mAb targeting *S. aureus* alpha-toxin for prevention of nosocomial pneumonia. Statistically significant Phase 2 data in the target population of those ≤ 65 years of age, was recently published in Lancet Infectious Diseases journal. The Company has completed discussions with the EMA and FDA on study design and expects to launch its Phase 3 study of AR-320 in mid-2022.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M (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. This program is licensed to the Serum Institute of India and Shenzhen Arimab.

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 CF patients.

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

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, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Cash, cash equivalents and restricted cash	$ 19,986	$ 8,232
Other current and noncurrent assets	$ 6,810	$ 6,885
Total assets	$ 26,796	$ 15,117
Total liabilities	$ 40,906	$ 23,798
Total stockholders' deficit	$ (14,110)	$ (8,681)
Total liabilities and stockholders' deficit	$ 26,796	$ 15,117

ARIDIS PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Grant revenue	$ 570	$ -	$ 1,535	$ 1,000
Operating expenses:				
Research and development	8,588	4,231	37,936	16,956
General and administrative	1,951	1,592	7,310	6,445
Total operating expenses	10,539	5,823	45,246	23,401
Loss from operations	(9,969)	(5,823)	(43,711)	(22,401)
Other (expense) income :				
Interest (expense) income, net	(247)	-	(245)	77
Other income	22	-	74	-
Gain on extinguishment of Paycheck Protection Program loan	-	-	722	-
Change in fair value of note payable	(33)	-	(33)	-
Share of loss from equity method investment	-	-	-	(9)
Net loss	$ (10,227)	$ (5,823)	$ (43,193)	$ (22,333)
Deemed dividends	(3,141)	-	(4,127)	-
Net loss available to common stockholders	$ (13,368)	$ (5,823)	$ (47,320)	$ (22,333)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	14,499,848	9,903,459	12,291,600	9,168,744
Net loss per share, basic and diluted	$ (0.92)	$ (0.59)	$ (3.85)	$ (2.44)

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