Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces First Quarter 2022 Financial Results and Business Update

Multiple clinical data readouts expected in second half of 2022

LOS GATOS, Calif., May 16, 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 first quarter ended March 31, 2022.

First Quarter Highlights

- Continued enrollment in the Company's Phase 2a study of AR-501 targeting cystic fibrosis (CF), conducted in collaboration with funding support from the CF Foundation. The top-line data from this CF study is now expected in 2H 2022.
- Continued enrollment in the Company's Phase 3 study evaluating AR-301 for the treatment of Ventilator Associated Pneumonia (VAP). Aridis remains on track to report top-line data in 2H 2022.
- The Company remains 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).
- Aridis remains on track to initiate a Phase 1/2 clinical trial late in the second half of 2022 to evaluate AR-701, a monoclonal antibody (mAb) cocktail, for the treatment of COVID-19 .

"We are on track to report top-line data from multiple clinical trials this year, including our Phase 2a study in CF and our Phase 3 study evaluating AR-301 for the treatment of VAP," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "We believe these data readouts, combined with the planned initiation of our Phase 3 trial of AR-320 and the first in-human study of AR-701 towards the end of this year, position Aridis for a pivotal year of important clinical milestones. We remain focused on building our leadership in the respiratory health space and appreciate the financial support of organizations like the Gates Foundation and European Commission's IMI program for these important therapeutic areas. We look forward to sharing further updates on the progress of our development programs in the weeks and months ahead."

Clinical Program Update

AR-501 (gallium citrate): Following the successful demonstration of safety in healthy adults in a Phase 1 clinical study, the Company initiated its Phase 2a study to evaluate the safety, pharmacokinetic (PK), and preliminary efficacy in cystic fibrosis (CF) patients. The Phase 2a study is actively enrolling patients with a goal of delivering full data readout in 2H 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 study underway is a randomized, double-blind, placebo-controlled Phase 2a trial investigating the safety and PK of multiple-ascending doses of inhaled AR-501 in 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-301 (tosatoxumab): AR-301 is being evaluated in a Phase 3 clinical study as an adjunctive treatment to standard of care antibiotics in *Staphylococcus aureus* VAP patients. The ongoing AR-301 Phase 3 study remains blinded, and the independent Data Safety Monitoring Committee with access to unblinded data continues to monitor study subjects and has not expressed any safety concerns. The Company observed modest improvement in enrollment in recent months despite the continued COVID-19 pandemic. However, because a significant number of participating clinical sites in the study are in Eastern Europe, the escalating Ukraine-Russia conflict is adding additional enrollment challenges. At the present time, the company anticipates reporting top-line data in the 2H 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): AR-320 is a fully human, IgG1 monoclonal antibody targeting *S. aureus* alpha toxin. AR-320 is active against infections caused by both methicillin resistant *S. aureus* 'MRSA' and methicillin resistant sensitive *S. aureus* 'MSSA'. 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. Details of the Phase 3 SAATELLITE-2 clinical trial can be viewed on https://www.clinicaltrials.gov using identifier: NCT05331885

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.

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 virus 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 towards the end of 2022.

First Quarter Financial Results:

- **Cash**: Total cash, cash equivalents and restricted cash as of March 31, 2022, were approximately $14.2 million. During the first quarter, the company received a second $5 million tranche from its non-dilutive loan facility with Streeterville Capital. The first $5 million tranche was received in November 2021.

- **Revenues:** Grant and licensing revenue increased to approximately $1.2 million for the quarter ended March 31, 2022 primarily due to the recognition of revenue from grants from the Cystic Fibrosis Foundation (CFF) and the Gates Foundation as well as from Kermode Biotechnologies, Inc., an Apex technology licensee. There was no grant and licensing revenue reported for the quarter ended March 31, 2021.

  Research and Development Expenses: Research and development expenses were $6.5 M in the quarter ended March 31, 2022, up from $5.0 M in the prior year period. The increase was due primarily to drug manufacturing expenses for our Phase 3 clinical trial evaluating AR-320 for the prevention of VAP ($1.0 M), other spending in preparation for the initiation of the AR-320 Phase 3 clinical trial ($0.8 M), and manufacturing of clinical supplies for the initiation of a Phase 1 clinical trial evaluating AR-701 for the treatment of COVID-19 ($0.5 M). These increases were offset by decreases in expenditures for our ongoing Phase 3 clinical trial evaluating AR-301 for the treatment of VAP ($0.7M) and on our ongoing Phase 2a clinical trial evaluating AR-501 for the treatment of cystic fibrosis ($0.1 M).

- **General and Administrative Expenses:** General and administrative expenses were $2.2 M for the quarter ended March 31, 2022, up from $1.9 M in the prior year period. The increase was due primarily to professional fees and an increase in salaries and wages.

- **Interest Income (Expense) net:** Net interest expense was approximately $0.4 M for the quarter ended March 31, 2022, up from no net interest income for the prior year period. The increased expense was primarily due to our debt servicing in Q1 2022.

- **Other Income:** Other income in the quarter ended March 31, 2022 was $22,000, an increase from $7,000 during the quarter ended March 31, 2021. This increase was primarily due to income from a sublease agreement we entered into with a tenant in March 2021 to sublet a small portion of our Los Gatos facility.

- **Net Loss:** The net loss available to common stockholders for the quarter ended March 31, 2022, was approximately $7.8 million, or $0.44 net loss per share, compared to a net loss available to common stockholders of approximately $7.9 million, or $0.77 net loss per share, for the quarter ended March 31, 2021. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was 17.7 million and 10.2 million for the quarters ended March 31 of 2022 and 2021, 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 published in the September 2021 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, 2021, 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.

Condensed Consolidated Balance Sheets

(In thousands)

	March 31, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	$ 12,475	$ 18,098
Other current and noncurrent assets	11,342	8,698
Total assets	$ 23,817	$ 26,796
Total liabilities	44,226	39,906
Total stockholders' deficit	(20,409)	(13,110)
Total liabilities and stockholders' deficit	$ 23,817	$ 26,796

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	(unaudited)
Revenue	$ 1,187	$ —
Operating expenses:		
Research and development	6,450	4,955
General and administrative	2,161	1,944
Total operating expenses	8,611	6,899
Loss from operations	(7,424)	(6,899)
Other income (expense):		
Interest (expense) income, net	(364)	1
Other income	22	7
Net loss	$ (7,766)	$ (6,891)

Deemed dividends	—	(986)
Net loss available to common stockholders	$ (7,766)	$ (7,877)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	17,701,592	10,230,043
Net loss per share to common stockholders, basic and diluted	$ (0.44)	$ (0.77)
Included stock based compensation as follows:		
Research and development	$ 166	$ 160
General and administrative	301	407
	$ 467	$ 567

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