Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Second Quarter 2022 Financial Results and Business Update

Multiple clinical data readouts expected in second half of 2022

LOS GATOS, Calif., Aug. 16, 2022 /PRNewswire/ -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies for treating life-threatening infections, today reported financial and corporate results for its second quarter ended June 30, 2022.

Second Quarter Highlights

- 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 from this study in 2H 2022.
- Continued enrollment in the Company's Phase 2a study of AR-501 targeting cystic fibrosis (CF), conducted in collaboration with funding support from the Cystic Fibrosis Foundation. Top-line data readout from this CF study is expected in 2H 2022.
- Initiated the Company's Phase 3 trial of AR-320 for the prevention of VAP following regulatory feedback on the clinical development plans from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). The study is conducted in collaboration with funding support from the European Commission's Innovative Medicines Initiative.
- Announced that the COVID-19 mAb cocktail AR-701 effectively eradicated virus from the lungs of SARS-CoV-2 infected macaque monkeys (non-human primates) and protected the lungs from the disease. The mAb cocktail was effective when administered by inhalation either prophylactically or therapeutically.

"The company is on track to report top-line data from the AR-301 Phase 3 study in ventilator associated pneumonia (VAP) and the AR-501 Phase 2a study in cystic fibrosis during the second half of 2022," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "We believe these data readouts will be significant and transformative milestones for the Company. In addition, we completed the manufacturing of the clinical trial supplies and launched the global Phase 3 trial of AR-320."

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 *Staphylococcus aureus* (*S. aureus*) VAP patients. The ongoing AR-301 Phase 3 study remains blinded. The independent Data Safety Monitoring Committee, which has access to unblinded data, continues to monitor study subjects and has not expressed any safety concerns. The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human mAb to treat acute pneumonia in the intensive care unit (ICU) setting. Details of the study can be viewed at www.clinicaltrials.gov using identifier NCT03816956. The Company continues to anticipate reporting top-line data in the late second half of 2022.

AR-501 (gallium citrate): The Phase 2a study is actively enrolling patients with the goal of delivering top-line data readout in second half of 2022. AR-501 is being developed in collaboration with and with funding support from the Cystic Fibrosis Foundation. The study is a randomized, double-blind, placebo-controlled Phase 2a trial investigating the safety and pharmacokinetics of multiple ascending doses of inhaled AR-501 in CF patients with chronic bacterial lung infections. The FDA reviewed the Phase 1 study results and agreed that the study could proceed at all dose levels to the Phase 2a portion of the Phase 1 / 2a trial in adult subjects with CF. Based on available blinded safety data of the on-going Phase 2a study, FDA also recently agreed with the Company's proposal to include an additional higher dose cohort. We expect to complete enrollment and announce study results in the second half of 2022. Details of the Phase 1 / 2a clinical trial can be viewed at https://www.clinicaltrials.gov using identifier NCT03669614.

AR-320 (suvratoxumab): AR-320 is a fully human immunoglobulin G1 (IgG1) monoclonal antibody (mAb) targeting *S. aureus* alpha toxin being developed as a preemptive treatment of mechanically ventilated ICU patients who are colonized with *S. aureus* but do not yet have VAP. AR-320 is active against infections caused by both methicillin resistant *S. aureus* (MRSA) and methicillin sensitive *S. aureus* (MSSA). 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 demonstrated a relative risk reduction in onset of pneumonia by 32% in the overall intent-to-treat study population, and by a statistically significant 47% relative risk reduction in the under 65-year-old population, which is the target population in the planned Phase 3 study. This risk reduction in the target population was also associated with a substantial reduction in the duration of care needed in the ICU and the hospital.

The Company completed successful discussions with the European Medicines Agency (EMA) via their Scientific Advisory meeting and with 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 launched the Phase 3 study (also referred to as 'SAATELLITE-2 Study') of AR-320 in collaboration with the public-private COMBACTE-Net consortium of HAP/VAP experts, funded by the Innovative Medicines Initiative 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 at https://www.clinicaltrials.gov using identifier: NCT05331885.

AR-701: AR-701 is a cocktail of two fully human 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 (CoV) 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). All authentic live SARS-CoV-2 Beta, Gamma, Delta, Epsilon, Omicron subvariants BA.1, BA.2, BA.4, BA.5, SARS-CoV, and MERS-CoV tested were neutralized by AR-701 *in vitro*. Multiple animal challenge models widely used to evaluate COVID-19 treatments support the broad efficacy of AR-701 against the original Wuhan wildtype strain, the Delta variants, the Omicron variants, and the severe acute respiratory syndrome virus (SARS). Each of the mAbs in the AR-701 cocktail was effective *in vitro* against the SARS-CoV-2 Omicron BA.1, BA.2, BA.4, BA.5 subvariants. Each of the mAbs conferred strong protection against Omicron BA.1 infected animals when given either parenterally or by intranasal administration. AR-701 was also shown to be effective in SARS-CoV-2 (COVID-19) infected macaque monkeys (non-human primates) when administered by inhalation, either prophylactically or therapeutically.

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 both as a self-administered inhaled formulation for the treatment of COVID-19 patients who are not yet hospitalized and as a long-acting intramuscular prophylactic to prevent COVID-19 infections. The potency of AR-701 and its direct delivery to the lungs by inhaled administration may facilitate broader treatment coverage and dose sparing not achievable by parenteral administration.

Aridis Pharmaceuticals recently received a grant from the Bill and Melinda Gates Foundation to evaluate the prevention of influenza and SARS-CoV2 viral transmission using inhaled delivery of monoclonal antibodies.

Second Quarter Financial Results:·

- **Cash**: Total cash, cash equivalents and restricted cash as of June 30, 2022 were approximately $8.0 million.
- **Revenues:** Grant and licensing revenue increased to approximately $0.3 million for the quarter ended June 30, 2022 primarily due to the recognition of revenue from grants from the Cystic Fibrosis Foundation, the Gates Foundation, as well as from Kermode Biotechnologies, Inc., an ʎPEX™ technology licensee. A total of $33,000 in grant and licensing revenue was reported for the quarter ended June 30, 2021.
- **Research and Development Expenses:** Research and development expenses increased by approximately $1.8 million from approximately $4.6 million for the quarter ended June 30, 2021 to approximately $6.3 million for the quarter ended June 30, 2022. The increase was primarily due to an increase in spending on clinical trial activities for AR-301, AR-501 and AR-320 offset by a decrease in spending on research and development activities for our COVID-19 programs, and a decrease in license and permit fees.
- **General and Administrative Expenses:** General and administrative expenses decreased slightly by approximately $13,000 to approximately $1.7 million for the quarter ended June 30, 2022 from approximately $1.7 million for the quarter ended June 30, 2021. This decrease was primarily due to reduction in stock compensation expense and state taxes, offset by an increase in personnel related costs and liability insurance.
- **Interest Income (Expense) net:** Net interest income was approximately $8,000 for the quarter ended June 30, 2022, compared to approximately zero interest income for the quarter ended June 30, 2021. The interest income was primarily due to interest earned on our cash-on-hand during the second quarter of 2022.
- **Other Income:** Other income increased to $23,000 for the quarter ended June 30, 2022, from approximately $22,000 for the quarter ended June 30, 2021. The income was primarily due to a sublease agreement we entered into with a tenant in March 2021 to sublet a small portion of our Los Gatos facility.
- **Gain on Extinguishment of Paycheck Protection Program Loan:** There was no extinguishment of debt for the quarter ended June 30, 2022. Gain on extinguishment of the Paycheck Protection Program loan was approximately $722,000 for the quarter ended June 30, 2021.
- **Change in Fair Value of Note Payable:** The fair value of note payable increased by $273,000 for the quarter ended June 30, 2022 compared to zero for the quarter ended June 30, 2021. The increase was due to an updated fair valuation calculation for our outstanding debt.
- **Common Stock:** During the three and six-month period ended June 30, 2022, the Company had not sold any shares of common stock under the ATM Sales Agreement. The ATM Sales Agreement facility currently

cannot be used without the Company updating certain required conditions. The Company presently has no plans to update such required conditions.

- **Net Loss:** The net loss available to common stockholders for the quarter ended June 30, 2022 was approximately $8.0 million, a $0.45 net loss per share, compared to a net loss available to common stockholders of approximately $5.5 million, a $0.49 net loss per share, for the quarter ended June 30, 2021. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was approximately 17.7 million and approximately 11.2 million for the second quarter 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 *S. aureus* alpha-toxin in VAP patients.

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-320 (VAP). AR-320 is a fully human mAb targeting *S. aureus* alpha-toxin for prevention of VAP. 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 recently launched the Phase 3 study.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that target multiple sites on the spike proteins of the SARS-CoV-2 virus.

AR-101 (HAP). AR-101 is a fully human IgM mAb in Phase 2 clinical development targeting *Pseudomonas 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-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.

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

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)

	June 30, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	$ 6,317	$ 18,098
Other current and noncurrent assets	10,369	8,698
Total assets	$ 16,686	$ 26,796
Total liabilities	$ 44,619	$ 39,906
Total stockholders' deficit	(27,933)	(13,110)
Total liabilities and stockholders' deficit	$ 16,686	$ 26,796

Aridis Pharmaceuticals, Inc

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
Grant revenue	$ 292	$ —	$ 1,479	$ —
License revenue	—	33	—	33
Total revenue	292	33	1,479	33
Operating expenses:				

Research and development	6,348	4,573	12,798	9,528
General and administrative	1,681	1,694	3,842	3,638
Total operating expenses	8,029	6,267	16,640	13,166
Loss from operations	(7,737)	(6,234)	(15,161)	(13,133)
Other income (expense):				
Interest income (expense), net	8	—	(240)	1
Other income	23	22	45	29
Gain on extinguishment of debt	—	722	—	722
Change in fair value of note payable	(273)	—	(389)	—
Net loss	$ (7,979)	$ (5,490)	$ (15,745)	$ (12,381)
Deemed dividends	$ —	$ —	$ —	$ (986)
Net loss available to common stockholders	$ (7,979)	$ (5,490)	$ (15,745)	$ (13,367)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	17,701,592	11,233,572	17,701,592	10,734,580
Net loss per share to common stockholders, basic and diluted	$ (0.45)	$ (0.49)	$ (0.89)	$ (1.25)

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