Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Second Quarter 2021 Results

-- In-licensed Phase 3-ready antibody, suvratoxumab, from AstraZeneca
-- Raised approximately $25 million in equity financing
-- Confirmed that SARS-CoV-2 antibody combination AR-712 is active against the Delta variant and all other strains on the CDC's Variants of Interest and Variants of Concern lists

LOS GATOS, Calif., Aug. 12, 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 its second quarter ended June 30, 2021.

Second Quarter Highlights

- Executed and announced in July an agreement with AstraZeneca under which the Company in-licensed the Phase 3-ready monoclonal antibody (mAb) candidate, suvratoxumab, being evaluated for the prevention of pneumonia. AstraZeneca took an equity stake in Aridis as part of the agreement and has first right of negotiation for future licensing of AR-320. Launch of the Phase 3 study, supported by up to €25 million (approximately $30 million) of funding from the EU Commission's Innovative Medicines Initiatives (IMI), is expected in the fourth quarter of 2021.

  Phase 2 data, involving n=196 patients, was recently published in The Lancet Infectious Diseases journal. The data showed that in the overall intent to treat (ITT) study population, mechanically ventilated ICU patients colonized with *Staphylococcus aureus* (*S. aureus*) treated with suvratoxumab saw a relative risk reduction of pneumonia of 32%. Importantly, in the pre-specified population under 65 years of age, which is the target population in the planned Phase 3 study, the relative risk reduction was, a statistically significant, 47%.

  Aridis believes that suvratoxumab (also referred to as 'AR-320') will be a first-line, first-to-market, first-in-class pre-emptive treatment of *S. aureus* colonized patients. The same first-line, first-to-market and first-in-class strategy applies to the company's Phase 3 candidate AR-301, which is being developed for the acute treatment of ventilator associated pneumonia (VAP) patients. AR-320 and AR-301 are highly complementary to each other, as AR-320 is expected to be beneficial in a prevention mode for patients who have been colonized by the *S. aureus* bacteria but who did not yet progress to VAP, while AR-301 is intended to treat patients who are diagnosed with VAP caused by *S. aureus*. With these complimentary product candidates, the Company believes it is in a position to be a global leader in the prevention and treatment of VAP caused by *S. aureus*.

- Announced on August 4 that it had closed a definitive agreement with a single healthcare-focused institutional investor for the purchase and sale of 4,947,556 shares of the Company's common stock (or common stock equivalents) and warrants to purchase up to an aggregate of 2,473,778 shares of the Company's common stock, at an effective at-the-market purchase price of $5.053 per share, in a registered direct offering priced at a premium to the market under Nasdaq rules. The gross proceeds to the Company from this offering was approximately $25 million, before deducting the placement agent's fees and other offering expenses payable by the Company. The Company intends to use the net proceeds from this offering for clinical development, working capital and general corporate purposes through early 2022.
- Inhaled COVID mAb combination (AR-712) binds and neutralizes SARS-CoV-2 Delta variant at a highly effective level (~20ng/mL). Binding analyses project that AR-712 will be effective against all variants on the U.S. Centers for Disease Control's Variants of Interest and Variants of Concern lists.
- AR-711, one of two mAbs in the AR-712 cocktail, is confirmed by the Coronavirus Immunotherapeutics Consortium (CoVIC; https://covic.lji.org) to be among the top five most potent when compared to more than 350 COVID-19 mAbs that entered the CoVIC evaluation program.
- Continued enrolling global Phase 3 clinical trial of AR-301 in patients with *S. aureus* VAP. Top-line data expected in mid-2022.

"We are delighted to have been selected by AstraZeneca as the licensee of its Phase 3-ready candidate for the prevention of pneumonia, and with the recent influx of cash from our latest capital raise and the substantial funding by the EU's Innovative Medicines Initiatives, we are in a great position to launch our Phase 3 study for AR-320 in the fourth quarter of this year," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Multiple near-term clinical milestones from our expanding product pipeline (AR-712 Phase 1 and 2 read-outs in 1H 2022, AR-501 Phase 2a data in Q1 2022 and AR-301 Phase 3 top-line data in mid-2022) should provide a number of strong catalysts to fortify our leadership position in the respiratory health space."

"I am delighted at the completion of the in-licensing agreement with AstraZeneca to bring suvratoxumab into the Aridis pipeline, as I have been involved in developing this highly promising mAb for almost a decade," commented Hasan Jafri, M.D., Chief Medical Officer of Aridis Pharmaceuticals. "After the favorable results of the Phase 2 study, this agreement enables Aridis to initiate a Phase 3 trial of suvratoxumab in partnership with the COMBACTE Consortium as part of its commitment to bring multiple novel immunotherapeutic molecules targeting antimicrobial resistance (AMR) to critically ill patients with high unmet medical need."

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* 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 conveyed any safety concerns (i.e., thus far an un-remarkable safety profile). However, the pace of the trial had been affected by the COVID-19 pandemic. The activation of AR-301 clinical trial sites progressed globally during the pandemic, but the patient enrollment slowed due to the prioritization of the intensive care units (ICU) around the world to COVID-19 patients. As countries start to emerge from the pandemic, the company expects patient enrollment to improve, and enrollment completed in late first half of 2022. At this rate, the Phase 3 interim futility analysis would be completed too close to the completion of patient enrollment to be useful. As such, the company will elect to forgo the interim futility analysis and focus on accelerating patient enrollment to deliver top-line data by approximately mid-2022.

It is important to note that COVID-19 patients on prolonged mechanical ventilation in the 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 likely 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 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 mAb 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: The Company initiated its Phase 2a study to evaluate the safety, pharmacokinetic, and preliminary efficacy evaluation in cystic fibrosis (CF) patients in the first quarter of 2021. The Phase 2a is actively enrolling patients with a goal of 42 cystic fibrosis adult patients at full enrollment. The Company expects to report top-line data from this study during the first quarter of 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 is a randomized, double-blinded, placebo-controlled single ascending dose and multiple ascending dose 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 Phase 1/2a clinical trial can be viewed on www.clinicaltrials.gov using identifier NCT03669614.

***AR-712*:** AR-712 is a cocktail of two mAbs, AR-711 and AR-720, designed to lower the barrier to treatment coverage of non-hospitalized SARS-CoV-2 (i.e., 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-CoV-2 virus. AR-712 binds and neutralizes the SARS-CoV-2 Delta variant virus at a highly effective level (~20ng/mL) and binding analyses project that AR-712 will be effective against all variants on the U.S. Centers for Disease Control's Variants of Interest and Variants of Concern lists. AR-711 is confirmed by the CoVIC consortium (NIAID, Bill and Melinda Gates Foundation, Wellcome Trust, MasterCard Impact Fund and others) to be among the top five most potent mAbs out of over 350 COVID-19 mAbs that entered the CoVIC evaluation program. In a mouse model of SARS-CoV-2 infection, the AR-711 mAb effectively protected infected animals at the lowest parenteral dose tested (0.5 mg/kg).

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 towards the end of 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.

AR-320 (suvratoxumab): The Company announced the licensing of this Phase 3-ready asset from AstraZeneca in July 2021. A multinational, randomized, double blinded, placebo-controlled Phase 2 study (n=196 patients) showed that mechanically ventilated ICU patients colonized with *S. aureus* who are treated with suvratoxumab, a fully human mAb, saw a relative risk reduction of pneumonia by 32% in the overall ITT study population, and by 47% in the under 65-year-old population, which is the target population in the planned Phase 3 study. The relative risk reduction in the target population reached statistical significance and was also associated with a substantial reduction in the duration of care needed in the ICU and hospital. The Company expects to launch its Phase 3 study of AR-320 in the fourth quarter of 2021.

Corporate Update

A key development was the closing of a $25 million financing which occurred in August 2021. The proceeds from this registered direct offering strengthened the Company's balance sheet subsequent to the second quarter to support the continued advancement of AR-301's Phase 3 VAP treatment clinical trial, while allocating the requisite resources to preparing for the initiation of a Phase 3 clinical evaluating AR-320, recently licensed from AstraZeneca, for the prevention of VAP, AR-501's Phase 2b cystic fibrosis clinical trial and the ongoing development of novel COVID-19 therapies, such as AR-712.

Fiscal 2021 Second Quarter Results:

- **Cash**: Total cash and cash equivalents as of June 30, 2021 were approximately $3.6 million.
- **Revenues:**
  - *Grant revenue* decreased to zero for the quarter ended June 30, 2021 from $1.0 million for the quarter ended June 30, 2020 due to the recognition of revenue related to a development-based milestone achieved under the award from the Cystic Fibrosis Foundation (CFF) during the second quarter of 2020 and none during the second quarter of 2021.
  - *License revenue* increased to approximately $33,000 for the quarter ended June 30, 2021 from zero for the quarter ended June 30, 2020 due to the recognition of revenue related to the out-licensing and product discovery agreement with Kermode Biotechnologies, Inc., which was entered into during the first quarter of 2021. There was no license revenue during the second quarter of 2020.
- **Research and Development Expenses:** Research and development expenses increased by approximately $926,000 from approximately $3.6 million for the quarter ended June 30, 2020 to approximately $4.6 million for the quarter ended June 30, 2021. The quarter over quarter increase was primarily due to an increase in spending on research and development activities for our COVID-19 programs, an increase in personnel, consulting and other related costs, and an increase in spending on clinical trial activities and drug manufacturing expenses for AR-301 and AR-501, currently undergoing clinical evaluation.
- **General and Administrative Expenses:** General and administrative expenses increased by approximately $111,000 from approximately $1.6 million for the quarter ended June 30, 2020 to approximately $1.7 million for the quarter ended June 30, 2021. This increase was due primarily to increases in professional service fees, personnel related costs, including stock-based compensation, and patent related expenses, partially offset by a decrease in Delaware franchise taxes.
- **Interest Income, net:** Interest income, net decreased by approximately $10,000 from approximately $10,000 for the quarter ended June 30, 2020 to approximately less than $1,000 for the quarter ended June 30, 2021, due primarily to lower average cash balances during the second quarter of 2021 as compared to the same period in 2020.
- **Other Income:** Other income increased by approximately $22,000 from zero for the quarter ended June 30, 2020 to approximately $22,000 for the quarter ended June 30, 2021, which relates 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. There was no sublease agreement or related income during the second quarter of 2020.
- **Gain on Extinguishment of Paycheck Protection Program Loan:** Gain on extinguishment of the Paycheck Protection Program loan of approximately $722,000 for quarter ended June 30, 2021 related to the forgiveness of our loan from the Small Business Administration and release of financial obligation from our lender, Silicon Valley Bank, in May 2021. There was no extinguishment of debt in 2020.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment was zero for the

second quarter of 2021 and the same period in 2020.
- **Net Loss:** The net loss available to common stockholders for the quarter ended June 30, 2021 was approximately $5.5 million, or $0.49 net loss per share, compared to a net loss available to common stockholders of approximately $4.2 million, or $0.47 net loss per share, for the quarter ended June 30, 2020. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was approximately 11.2 million and approximately 8.9 million for the second 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 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 (*S. aureus*). AR-320 is a fully human mAb for prevention of pneumonia with statistically significant Phase 2 data in the target population of those ≤ 65 years of age, recently published in Lancet Infectious Diseases journal. A Phase 3 study of AR-320, licensed from AstraZeneca, is expected to begin in the fourth quarter of 2021.

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 a cocktail of two fully human IgG1 mAbs, AR-711 and AR-720, 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)

	June 30, 2021	December 31, 2020
	(unaudited)	
Cash and cash equivalents	$ 3,592	$ 8,232
Other current and noncurrent assets	7,795	6,885
Total Assets	$ 11,387	$ 15,117
Total Liabilities	$ 24,874	$ 23,798
Total stockholders' deficit	(13,487)	(8,681)
Total liabilities and stockholders' deficit	$ 11,387	$ 15,117

Aridis Pharmaceuticals, Inc.

Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)		*(unaudited)*	
Revenue	$ 33	$ 1,000	$ 33	$ 1,000
Operating Expenses*				
Research and development	4,573	3,647	9,528	8,564
General and administrative	1,694	1,583	3,638	3,222

Total operating expenses	6,267	5,230	13,166	11,786
Loss from operations	(6,234)	(4,230)	(13,133)	(10,786)
Other income (expense)				
Interest income, net	—	10	1	71
Other income	22	—	29	—
Gain on extinguishment of Payroll Protection Program loan	722	—	722	—
Share of loss from equity method investment	—	—	—	(9)
Net loss	$ (5,490)	$ (4,220)	$ (12,381)	$ (10,724)
Deemed dividends	—	—	(986)	—
Net loss available to common stockholders	$ (5,490)	$ (4,220)	$ (13,367)	$ (10,724)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	11,233,572	8,923,374	10,734,580	8,921,383
Net loss per share available to common stockholders, basic and diluted	$ (0.49)	$ (0.47)	$ (1.25)	$ (1.20)
*Includes stock based-compensation as follows				
Research and development	$ 172	$ 130	$ 332	$ 275
General and administrative	381	393	788	725
	$ 553	$ 523	$ 1,120	$ 1,000

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