Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Second Quarter 2020 Results

SAN JOSE, Calif., Aug. 11, 2020 /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 second quarter ended June 30, 2020.

Second Quarter Highlights and Recent Developments

- Reported positive safety data in the healthy subject (Phase 1) portion of AR-501's Phase 1/2a clinical trial for treating chronic lung infections in patients with cystic fibrosis (CF). Safety and efficacy results from the Phase 2a portion in CF patients expected in 2H 2021
- Continued enrolling Phase 3 global clinical trial of AR-301 in patients with ventilator associated pneumonia (VAP) including patients who presented with VAP secondary to ventilator placement for COVID-19. Interim data expected in 2H 2020; full data in 2H 2021
- Directed ʎPEX™ platform's discovery capabilities towards treatments for pulmonary infectious diseases given the on-going COVID-19 pandemic
- Initiated mAb discovery and IND enabling studies for AR-701, a potential treatment or prophylaxis for COVID-19, ʎPEX's first fully human mAb cocktail directed at multiple envelope proteins on SARS-CoV-2
- Bolstered leadership team with appointment of Dr. Hasan Jafri as Chief Medical Officer
- Enhanced corporate profile by participating in leading healthcare dedicated investor forums

"The second quarter proved to be a strong period of progress as we continue on our mission to become the leader in developing novel anti-infective treatments for lung infections," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "In addition to advancing multiple early and clinical stage programs while ramping-up our ʎPEX™ platform's rapid discovery engine to identify targets for pulmonary infections, we were able to enhance our leadership team with the appointment of Dr. Hasan Jafri as Chief Medical Officer. Dr. Jafri solidifies our expertise in infectious disease immunotherapy utilizing mAbs given his specific experience developing similar programs during his tenure at AstraZeneca. As we head into the second half of the year, I firmly believe we are well positioned to advance our ongoing clinical studies of AR-301 for VAP and AR-501 for CF as well as potentially start a new trial for AR-701 for COVID-19."

ʎPEX™ Technology Platform and COVID-19 Program Update

During the quarter, and in response to the most pressing need of current times, Aridis was able to utilize its ʎPEX mAb discovery platform to generate AR-701, a fully human mAb cocktail derived from convalescent COVID-19 patients and directed at multiple envelope proteins on SARS-CoV-2 to enable broad coverage against SARS-CoV-2 variants and ensuring wide applicability across variants of the virus that may arise. During the quarter ended June 30, 2020, the Company went from collecting sera from convalescent COVID-19 patients at hospital centers in US and Europe to thousands of candidate mAbs, which highlights how ʎPEX can rapidly identify large number of drug candidates to SARS-CoV-2 and other potential emerging viral or bacterial pathogens.

Aridis utilizes its ʎPEX technology platform for the unbiased discovery of new and highly potent antibodies against pathogens including COVID-19. The ʎPEX platform is comprised of a silicon wafer-based array of nanoliter sized tissue micro-culture wells that enable rapid screening of antibody secreting cells, enabling discovery of potent antibodies against targets such as SARS-CoV-2, the virus that causes COVID-19 disease within a few days of patient sample availability. It also features CRISPR enabled activation of endogenous genetic control elements that dramatically increase the yield of such therapeutic antibodies from manufacturing production cell lines. The technology also features a proprietary production cell line that is designed to rapidly manufacture multiple monoclonal antibody therapeutics at approximately half the manufacturing cycle time than currently available manufacturing technologies.

Clinical Program Update

AR-301: Aridis remains on track to report interim data in 2H 2020, and top line data in 2H 2021 of its ongoing Phase 3 clinical trial of AR-301. While this timeline may be further impacted by the on-going COVID-19 pandemic, the pace of the trial was not significantly impacted in the second quarter. In fact, during April, Aridis enrolled its first COVID-19 patient in the study. 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, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 160 clinical centers in 22 countries. Participating clinical centers that are activated continue to follow the same 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-301 is a fully human monoclonal IgG1 antibody specifically targeting gram-positive *S. aureus* alpha-toxin. It has been shown *in vitro* to protect against alpha-toxin mediated destruction of host cells, thereby potentially preserving the human immune response. AR-301's mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both MRSA (methicillin resistant *S. aureus*) and MSSA (methicillin sensitive *S. aureus*).

AR-501: On June 22, 2020 Aridis reported positive safety data from the healthy subjects portion of its Phase 1/2a clinical trial of an inhalable formulation of gallium citrate being evaluated for the treatment of chronic lung infections associated with cystic fibrosis. There were no reports of serious adverse events and the treatment was well tolerated. The study was designed to enroll 48 healthy adult volunteers (Phase 1) and 48 cystic fibrosis patients (Phase 2a) from approximately 18 sites in the U.S. In the now-completed Phase 1 arm, 48 healthy adults were randomized and treated in 6 cohorts (of 8 subjects each) to receive either a single ascending dose (SAD, Cohorts 1, 2, and 3 [N=24]) or weekly multiple ascending doses (MAD, Cohorts 4, 5, and 6 [N=24]) of active drug at 6.4 mg gallium (Ga^{+3}), 20 mg Ga^{+3} and 40 mg Ga^{+3} or placebo. Phase 1 participants were randomized within each cohort in a 3:1 ratio of active drug to placebo. Subjects were followed for 28 days after study dose for safety and pharmacokinetics (PK) of inhaled AR-501 in HV subjects. AR-501 or placebo was delivered by a nebulizer device. Following the recommendations of the Data Safety Monitoring Board (DSMB) from the Cystic Fibrosis Foundation (CFF) and study's Safety Monitoring Committee (SMC), the Company will proceed with the Phase 2a segment with cystic fibrosis subjects and expects to report data in 2H 2021. The achievement of this milestone triggered a $1.0 million milestone payment from the CFF, and the Company recognized $1.0 million in revenue during the second quarter of 2020.

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 U.S. Food and Drug Administration (FDA). In addition, the European Medicines Agency (EMA) granted ODD to AR-501. Details of the Phase 1/2a clinical trial, which is a randomized, double-blinded, placebo controlled single and multiple dose-ascending trial investigating the safety and PK of inhaled AR-501 in healthy volunteers and cystic fibrosis patients with chronic bacterial lung infections, can be viewed on www.clinicaltrials.gov using identifier NCT03669614.

Corporate Update

During the second quarter, the Company enhanced its leadership team by appointing Dr. Hasan Jafri as Chief Medical Officer. Dr. Jafri brings to Aridis over 25 years of experience in clinical practice and research, especially in the area of serious healthcare associated and community acquired infections, respiratory viral infections and invasive fungal infections. Immediately prior to joining Aridis, Dr. Jafri was at AstraZeneca, where he most recently served as Senior Medical Director, Clinical Research and Development, Microbial Sciences, Clinical Head of Antibacterial mAb Program, and Coordinator of the European Public-Private COMBACTE-NET & COMBACTE-MAGNET consortia focused on antibacterial drug development supported by the Innovative Medicines Initiative (IMI). During his tenure at AstraZeneca, he led the clinical development of the anti-bacterial monoclonal antibodies within the Serious Bacterial Infections Franchise, including its Phase 2 programs MEDI4893 (anti-*S. aureus* alphatoxin mAb) and MEDI3902 (anti-*P. aeruginosa* Psl/PcrV mAb).

Throughout the quarter, Aridis continued to increase its profile in the investment and business communities by participating in leading healthcare dedicated investor forums. The Company's management team was hosted by Cantor Fitzgerald for a Fireside Chat on June 25th entitled "ΛPEX™, a technology platform geared to rapidly discover new treatments for emerging pulmonary pathogens." On June 30th, Dr. Vu Truong, the Company's CEO was also a featured speaker in another Cantor Fitzgerald symposium entitled "Winning Ways to Treat Infections and COVID-19." The event consisted of representatives from companies in various stages of development in the race to discover treatments for COVID-19.

Replays for both events can be found at https://investors.aridispharma.com/events.

Fiscal 2020 Second Quarter Results:

- **Cash**: Total cash and cash equivalents as of June 30, 2020 was $11.8 million.
- **Paycheck Protection Program Loan:** During the quarter ended June 30, 2020, the Company applied for and received a loan in the amount of approximately $715,000, pursuant to the Paycheck Protection Program.
- **Revenues:** Grant revenue increased to $1.0 million for the quarter ended June 30, 2020 from zero for the quarter ended June 30, 2019, which was primarily due to the recognition of revenue related to a milestone under the grant award from the CFF during the second quarter of 2020 and none during the second quarter of 2019.
- **Research and Development Expenses:** Research and development expenses incurred in the quarter ended June 30, 2020 were approximately $3.6 million, a decrease of approximately $3.0 million over the same period in 2019 due primarily to a decrease in spending on clinical trial activities and drug manufacturing expenses for the Phase 2 study of our AR-105 program, which terminated during 2019; a decrease in spending on our clinical trial activities and drug manufacturing expenses for the Phase 3 study of our AR-301 program during the second quarter of 2020 as compared to the second quarter of 2019, which included increased study start-up costs; and a decrease in personnel, consulting and other related costs. These decreases were partially offset by an increase in spending on clinical trial activities for the Phase 1/2a study of our AR-501 program.
- **General and Administrative Expenses:** There was no material difference in general and administrative expenses for the quarter ended June 30, 2020 when compared to the same period in 2019.
- **Interest Income, net:** Interest income, net was approximately $10,000 for the quarter ended June 30, 2020, a decrease of approximately $59,000 over the same period in 2019. This decrease was primarily due to lower interest rates.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment decreased by $186,000 for the quarter ended June 30, 2020 when compared to the same period in 2019 due to there being no share of losses from our equity method investment recorded in the second quarter of 2020 as the net book value of the investment was zero at March 31, 2020.
- **Net Loss:** The net loss for the quarter ended June 30, 2020 was approximately $4.2 million, or $0.47 net loss per share, compared to a net loss of approximately $8.4 million, or $1.03 net loss per share, for the quarter ended June 30, 2019. The weighted average common shares outstanding was approximately 8.9 million and approximately 8.1 million for the second quarter of 2020 and 2019, respectively.

About Aridis Pharmaceuticals, Inc.
Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as add-on treatments to standard-of-care antibiotics. 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 for high potency by the donor's immune system; hence, they do not require genetic engineering or further 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 preclinical stage 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 immunoglobulin 1, or 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 1/2a 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 fully human mAb cocktail discovered from convalescent COVID-19 patients that are directed at multiple envelope proteins on SARS-CoV-2.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb out-licensed preclinical program aimed at neutralizing diverse clinical isolates of respiratory syncytial virus (RSV).

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 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, 2019 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, 2020	December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 11,812	$ 20,897
Other current and noncurrent assets	6,303	7,070
Total Assets	$ 18,115	$ 27,967
Total Liabilities	$ 24,189	$ 24,331
Total stockholders' equity (deficit)	(6,074)	3,636
Total liabilities and stockholders' equity (deficit)	$ 18,115	$ 27,967

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended June 30,	Six Months Ended June 30,

	2020	2019	2020	2019
		(unaudited)		*(unaudited)*
Revenue	$ 1,000	$ —	$ 1,000	$ 1,022
Operating Expenses*				
Research and development	3,647	6,653	8,564	13,771
General and administrative	1,583	1,613	3,222	3,254
Total operating expenses	5,230	8,266	11,786	17,025
Loss from operations	(4,230)	(8,266)	(10,786)	(16,003)
Other income (expense)				
Interest income, net	10	69	71	185
Share of loss from equity method investment	—	(186)	(9)	(628)
Net loss	$ (4,220)	$ (8,383)	$ (10,724)	$ (16,446)
Weighted-average common shares outstanding, basic and diluted	8,923,374	8,107,290	8,921,383	8,106,484
Net loss per share, basic and diluted	$ (0.47)	$ (1.03)	$ (1.20)	$ (2.03)
*Includes stock based-compensation as follows:				
Research and development	$ 130	$ 198	$ 275	$ 371
General and administrative	393	338	725	615
	$ 523	$ 536	$ 1,000	$ 986

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