Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces First Quarter 2019 Results

SAN JOSE, Calif., May 14, 2019 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc.** (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of targeted immunotherapies using fully human monoclonal antibodies (mAbs) to treat life-threatening bacterial infections, today reported financial and corporate results for the first quarter ended March 31, 2019.

First Quarter Highlights

- Completed enrollment of global Phase 2 clinical trial of AR-105 as a treatment for ventilator-associated pneumonia (VAP) caused by *Pseudomonas aeruginosa (P. aeruginosa)*. Topline data expected in Q3 2019
- Initiated Phase 3 global clinical trial of AR-301 targeting gram-positive *Staphylococcus aureus* (*S. aureus)* in critically ill VAP patients. Interim data expected in Q1 2020 and top line data expected in late 2020
- Continued enrolling patients at a predicted rate in the Phase 1/2a clinical trial of AR-501, an inhalable therapy to treat chronic lung infections impacting cystic fibrosis patients. Top-line data expected in Q1 2020
- Filed for Orphan Drug Designation for AR-105 and AR-501 in U.S. and Europe

"I'm extremely pleased with the progress achieved during the quarter highlighted by reaching the enrollment completion milestone for AR-105's multi-national Phase 2 clinical trial. This is potentially a landmark study which accesses the clinical utility of using a targeted immunotherapy to treat a life threatening bacterial infection. We continue to be on track for a number of clinical data readouts, starting in the 3rd quarter of this year with AR-105, and in the 1st quarter of next year for AR-301 and AR-501," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals.

AR-105*:* The Company is pleased to report that during the first quarter, the enrollment for the program's global Phase 2 study was completed. AR-105 is a broadly active, fully human IgG1 monoclonal antibody targeting VAP caused by gram-negative *P. aeruginosa.* The trial enrolled 158 patients and the Company expects to have top-line data from the study in the third quarter of 2019. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03027609.

During the quarter, Aridis also filed for Orphan Drug Designation for AR-105 in U.S. and Europe. In the U.S., the FDA Office of Orphan Products Development grants orphan drug designation to drugs and biologics which are intended for the treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., and may provide grant funding toward clinical trial costs, tax advantages, FDA user-fee benefits, and seven years of market exclusivity in the U.S. In Europe, orphan designation is also a status assigned to a therapy intended for use in rare diseases. To be granted orphan status by the European Medicines Agency (EMA), the medicine must be intended for the treatment, prevention or diagnosis of a disease that is seriously debilitating and/or life threatening and has a prevalence of up to five in 10,000 in the European Union. Additionally, the intended medicine must aim to provide significant benefit to those affected by the condition.

AR-105 has the potential to treat all patient populations infected by *P. aeruginosa* and is not limited to any subset of *P. aeruginosa* infected patients. Therefore, pending the outcome of the Phase 2 trial, Aridis will evaluate whether there is a need to embark on a separate Phase 2/3 clinical trial for AR-101, another pipeline product which is a highly specific monoclonal antibody targeting *P. aeruginosa* lipopolysaccharide serotype O11 that accounts for a subset of approximately 22% of all *P. aeruginosa* hospital-acquired infections worldwide.

AR-301*:* During the first quarter, a key development milestone for the program was the initiation of a Phase 3 global clinical trial targeting gram-positive *S. aureus* in critically ill VAP patients. The trial will enroll 240 patients at approximately 140 clinical centers in 20 countries. Participating centers in all countries will follow the same stringent clinical protocols and procedures for critically ill VAP patients, as is standard in the U.S. and Europe. The Investigational New Drug (IND) application to include China among the patient enrolling countries in the study was accepted by the Chinese FDA. Interim data is expected in Q1 2020 and top line data expected in late 2020.

AR-301 is an intravenous, broadly active, 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*). 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 (ICU) setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

AR-501: During the first quarter, Aridis continued enrolling patients in its Phase 1/2a clinical trial of this inhalable formulation of gallium citrate being evaluated to treat chronic lung infections associated with cystic fibrosis with top-line data expected in Q1 2020. AR-501 is being developed in collaboration with the Cystic Fibrosis Foundation (CF Foundation) and has been granted by the FDA both Fast Track and Qualified Infectious Disease Product (QIDP) designations. The Fast Track designation provides the opportunity to accelerate AR-501's clinical development as it enables more frequent interactions with the FDA while also offering potential eligibility for priority review at the time of license application. The QIDP designation grants a five-year market exclusivity extension and provides priority review for the first application submitted for product approval.

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 pharmacokinetics 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. The study will accrue 48 healthy adult volunteers and 48 cystic fibrosis patients from approximately 15 sites in the U.S. During the quarter, Aridis also filed for Orphan Drug Designation for AR-501 in U.S. and Europe.

Fiscal First Quarter Results: $16.3 million in cash and cash equivalents as of March 31, 2019 with sufficient capital to fund operations into first quarter 2020

"Our expenses, and the resulting cash burn during the first quarter, were largely due to costs associated with launching the Phase 3 study of AR-301 and the Phase 1/2 study of AR-501. These studies' start-up phases have been largely completed, and we maintain our forecast of cash into the first quarter of 2020," commented Fred Kurland, Aridis' Chief Financial Officer.

- **Revenues:** Total revenues for the quarter ended March 31, 2019 were $1.0 million, an increase of $0.7 million over the similar period in 2018 primarily due to the adoption of ASC 606 and the recognition of an additional milestone related to the grant from the CF Foundation.
- **Research and Development Expenses:** Research and development expenses for the quarter ended March 31, 2019 were $7.1 million, an increase of $0.5 million over the similar period in 2018 due primarily to an increase in spending on clinical trial activities and drug manufacturing for our AR-301 program, partially offset by decrease in spending on drug manufacturing for our AR-105 program and a decrease in spending on toxicology studies related to our AR-501 program.
- **General and Administrative Expenses:** General and administrative expenses for the quarter ended March 31, 2019 were $1.6 million, an increase of $0.6 million over the similar period in 2018 due primarily to an increase in directors' and officers' liabilities insurance expense, an increase in Delaware franchise taxes, and increases in both personnel related expenses and professional service fees.
- **Interest and Other Income, net:** Interest and other income, net for the quarter ended March 31, 2019 was $116,000, an increase of approximately $42,000 over the similar period in 2018. These increases were due primarily to a higher rate of return on our cash balance partially offset by a lower average cash balance.
- **Change in Fair Value of Warrant Liability:** As a result of all warrants to purchase preferred stock being converted into warrants to purchase common stock upon our IPO in August 2018, there was no warrant liability recorded in the first quarter of 2019. There was a $38,000 increase in the fair value of warrant liability in the quarter ended March 31, 2018.
- **Net Loss:** The net loss available to common shareholders for the quarter ended March 31, 2019 was $8.1 million, or ($0.99) per share, compared to a net loss available to common shareholders of $8.2 million, or ($48.99) per share, for quarter ended March 31, 2018. It should be noted that there were 166,373 common shares outstanding during the first quarter of 2018 and until the completion of the Company's IPO in August 2018. Moreover, there were convertible preferred shares outstanding until the time of the IPO which earned dividends that were distributed as additional shares of preferred stock. All preferred shares were converted to common stock upon the completion of the IPO on August 16, 2018. There were 8.1 million common shares outstanding after the completion of the IPO when all preferred shares were converted to common shares. At December 31, 2018 and at March 31, 2019, there were 8.1 million shares common shares outstanding.

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 MabIgX® technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs. 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 and high mAb productivity. MabIgX® also allows for the selection of any antibody isotype depending on the optimal effector function required for treating the target infection. By bypassing the humanization and binding sequence optimization steps, and the entire process of generation of genetically

engineered antibody producing cell lines, MabIgX® enables high gross-margins and expedited progression to clinical development.

The Company has generated multiple clinical stage mAbs targeting bacteria that that cause life-threatening infections such as ventilator associated pneumonia (VAP) and hospital acquired pneumonia (HAP). 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 (ventilator associated pneumonia). AR-301 is a fully human immunoglobulin 1, or IgG1, mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in ventilator-associated pneumonia, or VAP, patients.

AR-105 (ventilator associated pneumonia). AR-105 is a fully human IgG1 mAb targeting gram-negative *P. aeruginosa* alginate in VAP patients. AR-105 is currently being evaluated in a global Phase 2 clinical study.

AR-101 (hospital acquired pneumonia). AR-101 is a fully human immunoglobulin M, or IgM, mAb targeting *P. aeruginosa* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide. A plan for the next clinical study will be communicated following the availability of Phase 2 clinical data for AR-105.

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-201 (RSV infection). AR-201 is a fully human IgG1 mAb 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 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, 2018 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, 2019 (unaudited)	December 31, 2018
Cash and cash equivalents	$ 16,311	$ 24,237
Other current and noncurrent assets	6,939	7,374
Total Assets	$ 23,250	$ 31,611
Total Liabilities	$ 4,541	$ 5,297
Total stockholders' equity	18,709	26,314
Total liabilities and stockholders' equity	$ 23,250	$ 31,611

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended March 31, (unaudited)	
	2019	2018
Revenue	$ 1,022	$ 322
Operating Expenses*		
Research and development	7,118	6,626
General and administrative	1,641	1,066
Total operating expenses	8,759	7,692
Loss from operations	(7,737)	(7,370)
Other income (expense)		
Interest and other income (expense), net	116	74
Change in fair value of warrant liability	-	(38)
Equity in net loss from equity method investment	(442)	-
Net loss	$ (8,063)	$ (7,334)
Preferred dividends	$ -	$ (817)
Net loss available to common stockholders	$ (8,063)	$ (8,151)
Weighted-average common shares outstanding, basic and diluted	8,105,636	166,373
Net loss per common share, basic and diluted	$ (0.99)	$ (44.08)
Preferred dividends, basic and diluted	$ -	$ (4.91)
Net loss per share available to common stockholders, basic and diluted	$ (0.99)	$ (48.99)

*Includes stock based-compensation as follows		
Research and development	$ 173	$ 141
General and administrative	277	362
	$ 450	$ 503

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