Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces 2018 Fourth Quarter and Year-End Financial Results and Business Update

SAN JOSE, Calif., March 28, 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 fourth quarter ended December 31, 2018. The Company, which is utilizing its proprietary MabIgX® antibody discovery platform to develop novel therapies for hospital acquired infections made considerable clinical development advances with its lead monoclonal antibody programs, AR-301 and AR-105, along with its cystic fibrosis (CF) candidate AR-501, an inhalable therapy to treat chronic lung infections impacting CF patients.

Fourth Quarter Highlights and Recent Developments

- The global Phase 2 clinical trial of AR-105 as a treatment for ventilator-associated pneumonia (VAP) caused by *Pseudomonas aeruginosa (P. aeruginosa)* expanded from 108 patients to at least 154 patients, and is within one month of completing patient enrollment. The Company expects to announce the readout of top-line data during Q3 2019
- Consensus received from the US Food & Drug Administration (FDA) and European Medicines Agency (EMA) on the initiation of a Phase 3 pivotal study of AR-301 targeting gram-positive *Staphylococcus aureus* (*S. aureus)* in critically ill VAP patients.
- Reached concurrence from US FDA and EMA for a globally harmonized Phase 3 clinical study design for AR-301 and acceptance of Clinical Cure as the primary endpoint. This study is initiated. Interim data expected in Q1 2020 and top line data expected in late 2020.
- Enrolled first subject in AR-501's Phase 1/2a clinical study in cystic fibrosis
- Expanded collaboration with Cystic Fibrosis Foundation for AR-501's development and received more than double the original funding award
- Received FDA Fast Track designation and Qualified Infectious Disease Product (QIDP) designation for AR-501
- Bolstered management with key hire to finance team

"The fourth quarter was an important development period for several of our core programs on clinical and corporate fronts," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "A major priority during the period was preparing for the upcoming launch of a pivotal Phase 3 study of AR-301 which is clearly a key milestone. Moreover, I'm equally pleased with the rapid progression of our AR-105 clinical trial and the launching of our AR-501 Phase 1/2a clinical study."

AR-105: An important fourth quarter clinical highlight was the continued enrollment progress of a multi-national Phase 2 study for AR-105, a broadly active, fully human IgG1 monoclonal antibody targeting VAP caused by gram-negative *P. aeruginosa*. Patient enrollment was rapid, enabling the Company to expand the study population from 108 to 154 patients in order to enhance the statistical powering of the study for a more definitive data readout. Patient enrollment is nearing completion. This allows the Company to be more precise about when top-line data will be available, i.e., the third quarter of 2019. 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 AR-105 study in Q3 2019, Aridis will decide 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: Aridis is pleased to report that during the fourth quarter, successful discussions with the FDA and EMA on the planned AR-301 clinical study led to agreements on the following:
1) A unified Phase 3 AR-301 clinical study design, which enables a globally harmonized clinical study
2) Stringent, objectively measured, clinically meaningful primary endpoint of Clinical Cure. This is significant for the VAP indication, as most previous anti-infective pivotal trials have been based on all-cause mortality as the primary endpoint, which involves a lengthy trial and large study population.
3) Ability to launch the Phase 3 clinical study in all territories concurrently. Approximately 130 clinical centers in twenty (20) countries, including China and India, will be involved in this study.

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. Following the diagnosis of severe pneumonia and confirmation of *S. aureus* in the patient's lung fluid, using either the classical microbiology test and/or a rapid diagnostic test, all participating patients will receive standard of care antibiotics in combination with either AR-301 immunotherapy or placebo. Details of the study can be viewed on www.clinicaltrials.gov website using identifier NCT03816956. The Company is planning to report an interim data readout in the first quarter of 2020, followed by topline data toward the end of 2020.

With regards to the Company's effort to initiate AR-301 Phase 3 clinical study in China, Aridis' joint venture with Shenzhen Hepalink Pharmaceuticals (called 'Shenzhen Arimab Biopharmaceuticals Ltd.') submitted a pre-Investigational New Drug briefing document ('Pre-IND') to the Chinese FDA (CFDA). The CFDA has provided comments to the Pre-IND, subsequent to which an IND was recently submitted to CFDA to formally request the allowance for launching a Phase 3 trial in China.

AR-501: During the fourth quarter, Aridis achieved multiple development milestones for AR-501, an inhalable formulation of gallium citrate that is being evaluated in collaboration with the Cystic Fibrosis Foundation for the treatment of chronic lung infections associated with the disease. The Company expanded its research agreement with the Cystic Fibrosis Foundation whereby the Foundation increased its funding support for the program from $2.9 million to a maximum of $7.5 million (contingent on Aridis achieving certain clinical milestones).

Another highlight for AR-501 was FDA granting both Fast Track designation and Qualified Infectious Disease Product (QIDP) designation for the program. 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.

Finally, Aridis announced the enrollment of the first patient in AR-501's Phase 1/2a clinical study 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 (details of the study can be viewed on www.clinicaltrials.gov website using identifier NCT03669614). The study will accrue 48 healthy adult volunteers and 48 cystic fibrosis patients from approximately 15 sites in the U.S. As part of the agreement between the Company and the Cystic Fibrosis Foundation in the AR-501 program, both parties will review the data from the Phase 1 portion of the Phase 1/2a study before it is reported to the U.S. FDA, which is expected in the first quarter of 2020. Together the Company and the Foundation could use this information to optimize the Phase 2a portion of the trial in the CF patients, if it is needed. This should not impact the targeted reporting time for the Phase 1 portion of the study which is anticipated in Q1 2020.

On the corporate front, Aridis enhanced its management team with the appointment of Michael A. Nazak as Vice President, Finance. Mr. Nazak is a seasoned financial executive with decades of experience managing teams of finance professionals at healthcare dedicated companies. His most recent position was senior Vice President, Finance and Administration at Coherus Biosciences, Inc., a publicly listed company on NASDAQ.

Fiscal Fourth Quarter Results: $24.0 million in cash and cash equivalents as of December 31, 2018 with sufficient capital to fund operations into first quarter 2020

- **Revenues:** Total revenues for 2018 were $2.8 million, an increase of $1.9 million over 2017. Grant revenue increased by approximately $1.5 million due primarily to the achievement of various milestones under our agreement with the CF Foundation. Collaboration revenue increased by approximately $0.4 million due to the termination of the GSK collaboration agreement, which resulted in the recognition of all remaining deferred revenue. Revenue for the quarter ended December 31, 2018 was $1.4 million, an increase of $0.6 million over the same period in the preceding year. Grant and collaboration revenues increased by $0.2 million and $0.4 million, respectively, for the same reasons as for the full calendar year.
- **R&D Expenses:** Research and development expenses for 2018 were $23.0 million, an increase of $5.6 million over 2017 due primarily to increased activity in our Phase 2 AR-105 clinical trial, manufacturing drugs for current and future trials and an increase in personnel related expenses. Research and development expenses incurred in the quarter ended December 31, 2018 were $5.6 million, an increase of $0.7 million over the similar period in 2017 due to increased spending on both AR-105 and AR-301 clinical trials.
- **G&A Expenses:** General and administrative expenses for 2018 were $3.9 million, an increase of $0.7 million over 2017 due primarily to an increase in professional services, personal related costs and other administrative expenses, partially offset by a decrease in patent related expenses. General and administrative expenses incurred in the quarter ended December 31, 2018 were $1.4 million, an increase of $0.7 million over the similar period in 2017 primarily due to an increase in non-cash stock-based

compensation charges, professional services, personnel related costs and other administrative expenses.

- **Interest and Other Income, net:** Interest and other income, net for the year ended December 31, 2018 was $0.4 million, an increase of approximately $0.2 million. Interest and other income, net was $0.2 million for the quarter ended December 31, 2018, an increase of $0.1 million over the similar period in 2017. These increases were due primarily to more interest income from a higher average cash balance after the completion of our IPO in August 2018.
- **Change in Fair Value of Warrant Liability:** Change in fair value of warrant liability for the year ended December 31, 2018 was a credit of $1.6 million, a $6.8 million improvement from an expense of $5.2 million incurred during 2017. There was no change in the fair value of warrant liability in the quarter ended December 31, 2018, an improvement from an expense of $0.6 million incurred during the similar period in the preceding year. These changes were due to a decrease in the underlying fair value of the Company's Series A convertible preferred stock prior to the time that the Company's Series A convertible preferred stock converted into common stock upon the Company's initial public offering in August 2018.
- **Net Loss:** The net loss available to common shareholders for the year ended December 31, 2018 was $23.5 million, or ($7.46) per share, compared to a net loss of $27.5 million, or ($164.98) per share, for year ended December 31, 2017. It should be noted that there were 166,373 common shares outstanding prior to the completion of the Company's IPO in August 2018. This number of common shares outstanding is unchanged from the beginning of calendar 2017. 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, there were also 8.1 million shares common shares outstanding.

About Aridis Pharmaceuticals, Inc.
Aridis Pharma 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 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 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)

	As of December 31,	
	2018	2017
Cash and cash equivalents	$ 24,237	$ 25,096
Other current and noncurrent assets	7,374	1,382
Total Assets	$ 31,611	$ 26,478
Total Liabilities	$ 5,297	$ 15,042
Total Convertible preferred stock	-	74,202
Total stockholders' equity (deficit)	26,314	(62,766)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 31,611	$ 26,478

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenues	$ 1,391	$ 794	$ 2,757	$ 860
Operating Expenses*				
Research and development	5,583	4,600	23,000	17,438

General and administrative	1,385	646	3,874	3,160
Total operating expenses	6,968	5,246	26,874	20,598
Loss from operations	(5,577)	(4,452)	(24,117)	(19,738)
Other income (expense)				
Interest and other income, net	158	72	420	234
Change in fair value of warrant liability	-	(563)	1,632	(5,152)
Equity in net loss of equity method investment	(19)	-	(40)	-
Net loss	$ (5,438)	$ (4,943)	$ (22,105)	$ (24,656)
Preferred dividends	$ -	$ (770)	$ (1,357)	$ (2,793)
Net loss available to common stockholders	$ (5,438)	$ (5,713)	$ (23,462)	$ (27,449)
Weighted-average common shares outstanding, basic and diluted	8,104,757	166,373	3,146,632	166,373
Net loss per common share, basic and diluted	$ (0.67)	$ (29.71)	$ (7.02)	$ (148.20)
Preferred dividends, basic and diluted	$ -	$ (4.63)	$ (0.43)	$ (16.78)
Net loss per share available to common stockholders, basic and diluted	$ (0.67)	$ (34.34)	$ (7.45)	$ (164.98)
*Includes stock based-compensation as follows				
Research and development	$ 22	$ 158	$ 461	$ 385
General and administrative	353	162	1,197	1,223
	$ 375	$ 320	$ 1,658	$ 1,608

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