Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Third Quarter 2018 Financial Results and Corporate Overview

- Completed an initial public offering on August 16 and began trading on the Nasdaq Capital Market
- Maintained the pace of patient enrollment of the AR-105 global Phase 2 clinical study; on track for study completion mid-2019
- Phase 3 clinical study launch of AR-301 and initiation of AR-501 Phase 1/2a on pace to occur near year end 2018
- Strengthened patent estate with additional issued patents

SAN JOSE, Calif., Nov. 13, 2018 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS)**, a biopharmaceutical company focused on the discovery and development of targeted immunotherapies using fully human monoclonal antibodies, or mAbs, to treat life-threatening infections, today announces financial results, a company update and product overview for the three and nine months ended September 30, 2018.

On August 16, 2018, Aridis completed its initial public offering of 2.2 million shares of its common stock which included an overallotment of 192,824 shares that was exercised on August 30 resulting in net proceeds of approximately $25.1 million. As of September 30, 2018 Aridis had cash and cash equivalents of $34.1 million, which management believes is sufficient to fund operations into 2020. These resources are expected to enable the Company to advance its multi-product clinical pipeline toward the achievement of key clinical milestones in 2018 and 2019.

"We are very pleased to have successfully completed our recent IPO and are grateful to our new and existing investors for their enthusiastic participation and continued support," said Vu Truong, Ph.D., Founder and CEO of Aridis. "The proceeds from the IPO will enable us to advance our clinical and preclinical pipeline of novel, fully human, anti-infective monoclonal antibodies targeting serious, potentially life-threatening infections toward near-term clinical milestones, including initiation of the AR-301 Phase 3 clinical study around the end of this year."

Dr. Truong added, "We believe that the future treatment of life-threatening infections, such as hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP), will shift toward a targeted approach, using drugs that are specific to just the pathogen that is infecting the patient, rather than drugs that induce a broad spectrum killing effect such as the current standard of care antibiotics. We are pleased that patient enrollment in the global Phase 2 clinical study evaluating AR-105 for the treatment of VAP is steady as expected. Thus, we remain on track to report top-line data from this study in mid-2019."

Product Overview and Clinical Progress

- AR-301, a broadly active, fully human monoclonal IgG1 antibody, specifically targets gram-positive *Staphylococcus aureus (S. aureus)* alpha-toxin. AR-301 has been shown to protect against alpha-toxin mediated destruction of host cells, thereby 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*).

  Aridis has presented positive Phase 1/2a safety data and efficacy trends from a double-blinded, placebo-controlled clinical study testing AR-301 in patients with severe pneumonia caused by *S. aureus.* In the study, patients treated with AR-301 in combination with antibiotics demonstrated less time spent on mechanical ventilation for VAP patients and higher rates of *S. aureus* eradication as compared to those treated with antibiotics alone. No drug-related serious adverse events were reported.

  The data from this study were published in the October 21, 2018 issue of *Intensive Care Medicine* in an article titled "Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial," and in the October 31, 2018, online edition of *The Lancet Respiratory* in an article titled "Safety and tolerability of AR-301 in patients with severe pneumonia." The data were also presented by Dr. Pierre-Francois Laterre at the 31st congress of the European Society of Intensive Care Medicine in Paris, France.

  Aridis intends to initiate a Phase 3 clinical study evaluating AR-301 near the end of 2018. The Phase 3 clinical study protocol was submitted to the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for review. A preliminary response from the FDA to the clinical study protocol has been received. Aridis has provided responses that have been incorporated into the study protocol and

submitted as an amended Investigational New Drug (IND) application to the FDA. A response from the EMA to the clinical protocol is expected this month. Our goal is to have a globally harmonized Phase 3 clinical study that would allow for submission of product license applications to these regulatory authorities in the same time frame. Approximately 120 clinical sites across 18 countries are expected to participate in this study. AR-301 has been granted Fast Track designation by the FDA and Orphan Drug designation in the European Union.

- AR-105, a broadly active, fully human IgG1 monoclonal antibody targeting HAP/VAP caused by gram-negative *Pseudomonas aeruginosa (P. aeruginosa),* has successfully completed a Phase 1 clinical study, demonstrating safety up to doses of 20 mg/kg. A worldwide Phase 2 clinical study of AR-105 in VAP patients infected with *P. aeruginosa* was initiated in the second quarter of 2017 and is actively enrolling patients. As noted above, the Company is on track to report top-line results from this study in mid-2019. AR-105 has been granted Fast Track designation by the FDA.

- AR-101 is a highly specific monoclonal antibody targeting HAP/VAP caused by gram-negative bacteria, *P. aeruginosa* lipopolysaccharide serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital-acquired infections worldwide. AR-101 has successfully completed Phase 2a clinical testing in HAP/VAP patients, demonstrating strong safety and efficacy trends. A Phase 2/3 clinical study is planned for 2019. AR-101 has received Orphan Drug designation from the FDA and EMA.

- AR-501 (gallium citrate) is an inhalable anti-infective therapy for the management of chronic lung infections in cystic fibrosis patients. AR-501 exhibits broad antimicrobial activity against gram-negative and gram-positive bacteria including antibiotic resistant strains in free-living, or planktonic, and biofilm communities, as well as against fungi. The Company believes AR-501's unique combination of broad-spectrum antimicrobial activity against pathogens, lower propensity to develop resistance than current inhaled antibiotics and less frequent dosing as compared to the current standard of care make it an ideal candidate for treatment of chronic polymicrobial infections, such as lung infections in cystic fibrosis patients.

  Clinical data from two studies of intravenous gallium, a Phase 1b and a Phase 2, conducted by the University of Washington (Seattle) in cystic fibrosis patients showed that a single intravenous dose (200 mg/m^2) resulted in evidence of lung function improvements and a positive safety profile. The Company believes that the intravenous data is encouraging and provides a strong rationale for local inhaled delivery. This route of administration is expected to provide a substantially higher therapeutic index and lower systemic exposure than the intravenous route of administration.

  The development of this product candidate is funded by the Cystic Fibrosis Foundation (CFF) through a Phase 1/2a trial. Aridis has filed an IND application and received FDA concurrence to proceed to trial initiation. The Company plans to initiate a Phase 1/2a trial in healthy adults and cystic fibrosis patients in the fourth quarter of 2018. The CFF has awarded Aridis a grant in excess of $2.9 million to fund this activity.

Additional Q3 Highlights

- In September 2018, Aridis announced a further strengthening of its intellectual property portfolio with receipt of a Notice of Allowance from the U.S. Patent & Trademark Office for U.S. Patent Application No**.** 15/427,976; 15/896,791, 15/896,711. This patent provides for additional broad patent coverage concerning multiple targets including gram-negative bacteria, *Acinetobacter baumannii*, and the Company's monoclonal antibodies AR-201 and AR-401. Since then, additional patents for AR-401 have been issued in several other countries. A strong patent estate is key to protecting Aridis' valuable intellectual property and the Company continues to aggressively build on its global patent estate.

- On February 11, 2018, Aridis Pharmaceuticals and Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (Shenzhen), a People's Republic of China company, formed a joint venture company called Shenzhen Arimab Biopharmaceuticals Co., Ltd., or SABC, a People's Republic of China company, to develop, manufacture, import and distribute AR-101 and AR-301 in China, Hong Kong, Macau and Taiwan. On August 6, 2018, the Company entered into an amendment to the JV Agreement with Hepalink whereby the Company agreed to additionally contribute an exclusive, revocable, and royalty-free right and license to its AR-105 product candidate in the Territory. Pursuant to the JV Agreement and the amendment, Hepalink initially owns 51% of the JV Entity and is obligated to contribute the equivalent of $7.2 million to the JV Entity. Hepalink is obligated to make an additional equity investment of at least $10.8 million into the JV Entity at the time of the JV's first future financing.

- Lynne M. Deans, MT, ASCP, joined Aridis in September as the Executive Director of Clinical Operations. Ms. Deans has decades of experience in directing global clinical drug development teams in infectious diseases

and several other therapeutic areas for both public and private companies.

Fiscal Third Quarter Results

- **Revenues:** Aridis' revenues are generated primarily from a grant and a collaboration. Total revenues were $1.0 million for the third quarter of 2018 compared to minimal revenue in the third quarter of 2017, as well as for the second quarter of 2018. The increase in $1.0 million compared to either period was primarily due to milestones met with respect to a grant from the CFF.

- **Operating Expenses:** Total operating expenses for the third quarter of 2018 were $7.6 million compared to $5.5 million for the third quarter of 2017 and $4.6 million for the second quarter of 2018.

- **R&D Expenses:** Third quarter research and development expenses were $6.9 million compared to $4.9 million for the comparable period in 2017 and $3.9 million for the second quarter of 2018. These increases of $2.0 million and $3.0 million respectively were primarily due to increased enrollment and activity in the Phase 2 clinical study evaluating AR-105 for the treatment of VAP as well as additional activity in servicing the CFF grant.

- **G&A Expenses:** Third quarter general and administrative expenses were $0.7 million compared to $0.6 million for the comparable period in 2017 and $0.7 million for the second quarter of 2018. The increase in the third quarter was due primarily to an increase in directors and liabilities insurance costs and stock compensation expenses.

- **Change in Fair Value of Warrant Liability:** The Company incurred a loss of $1.4 million in the third quarter of 2018 compared to a gain of $4,000 in the comparable period of 2017 and a gain of $3.1 million in the second quarter of 2018. The gains and losses are the result of changes in the underlying value of the convertible preferred stock with which the warrants are associated. Effective upon our initial public offering, these preferred stock warrants were converted into warrants to purchase common stock. This conversion reclassified the warrants from a liability on the balance sheet to additional paid-in-capital.

- **Net Loss:** Third quarter net loss was $7.9 million, or ($1.97) per share, compared to a net loss of $5.4 million, or ($32.57) per share, for the third quarter of 2017. This compares to a net loss of $1.4 million, or, ($8.56) per share for the second quarter of 2018. It should be noted that there were 166,373 common shares outstanding prior to the completion of the Company's IPO. This number of common shares outstanding is unchanged from the third quarter of 2017. Moreover, there were convertible preferred shares outstanding during that period 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 shares outstanding after the completion of the IPO when all preferred shares were converted to common shares.

About Aridis' mAbs

Fully human monoclonal antibodies (mAbs) against infectious disease targets are a growing area of interest as a therapeutic modality due to their strong safety profile in humans, long plasma half-life and low risk of drug resistance. Aridis has developed a suite of proprietary human mAbs as anti-infective drugs targeting key human pathogens, including *S. aureus* (MRSA & MSSA), *P. aeruginosa, A. baumannii* bacteria and respiratory syncytial virus, or RSV.

About Aridis' MabIgX® Antibody Discovery Platform

Aridis' MabIgX® technology is designed to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection. Aridis' proprietary fusion cell line immortalizes active, antibody-producing human B-cells with remarkable stability, enabling large-scale manufacturing of these fully human mAbs to be used as possible therapies to protect the general population.

Unlike current antibody therapies being developed for infectious diseases, Aridis' mAbs are completely of human origin, functionally optimized for high potency by the patient's immune system, and do not require genetic engineering or further optimization to achieve full functionality and high mAb productivity. This technology also allows for the selection of any antibody isotype, depending on the optimal effector function required for treating the target infection. Bypassing the humanization, binding sequence optimization, and generation of genetically

engineered antibody producing cell lines allows for a much faster progression to clinical development compared to other companies developing antibody therapies.

Key competitive advantages of Aridis' MabIgX® antibody discovery platform and the resulting fully human mAbs include:

- Faster progression from target identification to clinical development (by ~1 year) as compared to conventional immunotherapy approaches involving generations of genetically engineered antibody producing cell lines
- Antibody candidates are immunologically and medically relevant, based on specificity and isotype (e.g. IgG, IgA, IgM)
- Superior safety profile with the potential for long term, repeated administrations
- High affinity and selectivity may result in lower effective doses, resulting in lower cost-of-goods during large-scale production compared to traditional antibody therapies

About Aridis Pharmaceuticals, Inc.

Aridis (Nasdaq: ARDS) is a late-stage biopharmaceutical company focused on discovering and developing targeted immunotherapies using fully human monoclonal antibodies, or mAbs, to treat life-threatening infections. The use of mAbs represents an innovative treatment approach that harnesses the human immune system to fight infections and is designed to overcome the deficiencies associated with the current standard of care, broad spectrum antibiotics. Such deficiencies include, but are not limited to, increasing drug resistance, short duration of response, perturbation of the human microbiome and lack of differentiation among current treatments. Aridis' pipeline includes AR-101, a fully human immunoglobulin mAb targeting *P. aeruginosa* serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired infections worldwide; AR-301, a fully human immunoglobulin 1, or IgG1, mAb targeting hospital-acquired pneumonia, or HAP, and ventilator-associated pneumonia, or VAP, *S. aureus* alphatoxin; AR-105, a fully human IgG1 mAb being developed to treat acute pneumonia caused by *P. aeruginosa* infection; AR-501, a broad spectrum small molecule anti-infective being developed to manage chronic lung infections in cystic fibrosis patients; AR-401, the Company's preclinical mAb program aimed at treating infections caused by *Acinetobacter baumannii*; and AR-201, a fully human IgG1 mAb that neutralizes 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 a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof. 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, except share and per share amounts)

	September 30,	**December 30**

	2018	2017
Cash and cash equivalents	$ 34,077	$ 25,096
Other current & noncurrent assets	$ 4,496	$ 1,382
Total assets	$ 38,573	$ 26,478
Total liabilities	$ 7,203	$ 15,042
Total convertible preferred stock	$ -	$ 74,202
Total stockholders' deficit	$ 31,370	(62,766)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 38,573	$ 26,478

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$ 1,022	$ 22	$ 1,367	$ 67
Operating expenses*				
Research and development	6,907	4,859	17,418	12,836
General and administrative	735	649	2,489	2,516
Total operating expenses	7,642	5,508	19,907	15,352
Loss from operations	(6,620)	(5,486)	(18,540)	(15,285)
Other income (expense):				
Interest and other income (expense), net	119	64	262	162
Change in fair value of warrant liability	(1,388)	4	1,632	(4,589)
Loss from equity method investment	(20)	-	(20)	-
Net loss	$ (7,909)	$ (5,418)	$ (16,666)	$ (19,712)
Preferred dividends	$ (5)	$ (788)	$ (1,357)	$ (2,023)

Net loss available to common stockholders	$ (7,914)	$ (6,206)	$ (18,023)	$ (21,735)
Weighted-average common shares outstanding, basic and diluted	4,019,459	166,373	1,469,623	166,373
Net loss per common share, basic and diluted	$ (1.97)	$ (32.57)	$ (11.34)	$ (118.49)
Preferred dividends, basic and diluted	$ (0.00)	$ (4.73)	$ (0.92)	$ (12.16)
Loss per share available to common stockholders, basic and diluted	$ (1.97)	$ (37.30)	$ (12.26)	$ (130.65)
*Includes stock-based compensation as follows				
Research and development	$ 159	$ 92	$ 439	$ 218
General and administrative	235	111	745	971
	$ 394	$ 203	$ 1,184	$ 1,189

Contact:

Lisa Sher
Head of Investor & Public Relations
Sherl@aridispharma.com
+1 (970) 987-2654 (Direct)

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