Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces 2019 Fourth Quarter and Year-End Financial Results and Business Update

SAN JOSE, Calif., April 8, 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 bacterial infections, today reported financial and corporate results for the fourth quarter ended December 31, 2019.

Fourth Quarter Highlights and Recent Developments

- Continued enrolling Phase 3 global clinical trial of AR-301 in patients with ventilator associated pneumonia (VAP)
- Continued enrolling AR-501's Phase 1/2a clinical trial with top-line data provisionally expected in 1H 2020 (healthy subjects), and in 2H 2021 (cystic fibrosis subjects)
- Revised forecasts on interim and top-line AR-301 data readouts provisionally to 2H 2020 and 2H 2021, respectively, due to delays related to the on-going COVID-19 pandemic
- Enhanced leadership team with appointments of Dr. Paul Mendelman, Interim Chief Medical Officer and Michael A. Nazak, Chief Financial Officer
- Announced APEX™, a novel monoclonal antibody ("mAb") discovery, production and yield maximizing technology platform
- Presented a comprehensive profile of APEX™ at the World Vaccine & Immunotherapy Congress West Coast 2019 and Antibody Engineering & Therapeutics conferences
- Granted one additional patent, bringing the total to seven (7) patents granted in 2019 and expanding the patent estate to 65 issued patents and 20 pending patents

"The fourth quarter was an excellent period of clinical and corporate development progress," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "As we head into 2020, we will closely monitor the on-going COVID-19 pandemic and assess its impact on our business, including the impact on enrollment for the AR-301 Phase 3 and AR-501 clinical studies. COVID-19 also presents a rare opportunity to utilize the Company's APEX™ platform technology to develop differentiated, effective therapeutic solutions to fight this deadly pandemic. I am pleased to announce that our team of scientists are hard at work on this important task, and look forward to announcing the preliminary results in the coming months."

APEX™ Technology Platform and Clinical Program Update

In December, the Company announced APEX™, a novel monoclonal antibody ("mAb") discovery, antibody production and yield maximizing technology platform. APEX™ builds upon Aridis' original hybridoma-based technology platform, MabIgX®, which allows for rapid fusion and production of mAbs directly from patients antibody-producing B-cells.

APEX™ is being utilized for the rapid discovery of new and highly potent antibodies against pathogens and deploys a methodology to maximize the production/yield of selected antibodies on commercial scale. The technology is comprised of a silicon wafer-based array of nanoliter sized microculture wells that enables rapid screening of antibody secreting cells at large scale (>1 million single cells), enabling discovery of potent antibodies against targets such as viruses within a few days of a pandemic outbreak. It also features gene-editing enabled activation of endogenous genetic control elements that dramatically increase the yield of biotherapeutic drugs from manufacturing production cell lines. The technology further comprises a proprietary production cell line that is designed to rapidly manufacture multiple monoclonal antibody therapeutics at approximately half the manufacturing cycle time than current available manufacturing technologies.

APEX™ is expected to facilitate the rapid discovery and production of critical therapies for companies operating in the biopharmaceutical, biomanufacturing and biosimilar space. During the fourth quarter, Aridis entered into its first business development transaction for the platform, a research collaboration with Mapp Biopharmaceutical, Inc, a company incorporated in the U.S. ("MappBio"). Under the terms of the agreement, Aridis will apply its APEX™ technology to develop mAb productivity enhanced versions of an undisclosed number of CHO cell lines that were originally developed by MappBio.

Recently, Aridis presented a comprehensive profile of the APEX™ platform at the antibody and cell engineering conferences World Vaccine & Immunotherapy Congress West Coast 2019 and Antibody Engineering (San Francisco, CA) & Therapeutics (San Diego, CA). To access the presentation, please visit the "Publications and Posters" page within the Investors section of the Aridis Pharmaceuticals website at https://investors.aridispharma.com/overview.

Clinical Program Update

AR-301: The AR-301 trial, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 160 clinical centers in 22 countries. The advent of coronavirus infections in the fourth quarter has begun to impact the global patient enrollment rate, and delayed further clinical site activations in regions with large number of clinical sites, such as in China and India. Pending the resolution of the coronavirus pandemic, Aridis is provisionally expecting interim data to be reported in 2H 2020, and top line data in 2H 2021. 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: During the fourth quarter, Aridis continued enrolling patients in its Phase 1/2a clinical trial of this inhalable formulation of gallium citrate being evaluated for the treatment of chronic lung infections associated with cystic fibrosis. The single ascending dose cohorts of healthy subjects have completed dosing and the safety monitoring committee has recommended proceeding into the multiple ascending dose cohorts. The Company expects to report data from the Phase 1 portion of the trial which consists of healthy subjects provisionally in 1H 2020 and the Phase 2a segment with cystic fibrosis subjects in 2H 2021.

AR-501, which is being developed in collaboration with the Cystic Fibrosis Foundation (CFF), has been granted both Fast Track and Qualified Infectious Disease Product Designation (QIDP) designations by the U.S. Food and Drug Administration (FDA). In addition, during the third quarter (July 19th), the EMA granted the program Orphan Drug Designation (ODD). The FDA had granted ODD status to AR-501 in June 2019.

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 is expected to accrue 48 healthy adult volunteers and 48 cystic fibrosis patients from approximately 15 sites in the U.S.

Corporate Update

During the fourth quarter, the Company enhanced its leadership team by appointing Paul Mendelman, MD as interim Chief Medical Officer and Michael A. Nazak as Chief Financial Officer.

Dr. Mendelman brings to Aridis a prolific career in infectious diseases across industry and academia spanning over 30 years with board certification in pediatrics and pediatric infectious diseases. He has held senior clinical development positions at leading companies such as Takeda Vaccines (Vice President, Medical), MedImmune (Vice President & Therapeutic Area Leader, Clinical Development), and Merck (Director, Clinical Research Infectious Diseases). From 1996 to 2005, he managed the clinical development group for FluMist®, the live attenuated intranasal influenza vaccine, licensed initially in the U.S. for the 2003-04 season. Dr. Mendelman earned his BS and MD degrees at The Ohio State University, and completed post-graduate training at the University of Colorado Medical Center in Denver. His infectious disease fellowship at the University of Washington, School of Medicine, and Seattle Children's Hospital was followed by his joining that faculty and later serving as consulting Professor of Pediatrics at Stanford University School of Medicine. He has published over 100 articles in peer-reviewed journals and authored many published book chapters.

Mr. Nazak, who joined Aridis in November 2018, had been serving as Vice President, Finance. He is a seasoned financial executive with extensive experience managing teams of finance professionals at healthcare dedicated companies. Prior to joining Aridis, he served as Senior Vice President, Finance at Coherus Biosciences, Inc., a publicly listed company on Nasdaq. Previously he was the Senior Director of Finance & Accounting at InteKrin Therapeutics Inc., a biopharmaceutical company. Prior to that, Mr. Nazak served as the Corporate Controller for Reliant Technologies, Inc., a developer and manufacturer of medical laser devices, and as a Senior Director of Finance & Corporate Controller at Connetics Corporation, a then publicly-traded specialty pharmaceutical company. Mr. Nazak also held Corporate Controller and other finance and accounting positions at Cygnus Solutions (a Red Hat company), and MIPS Computer Systems, and was previously an auditor with Coopers & Lybrand LLP. Mr. Nazak is a Certified Public Accountant (inactive), and holds a B.S. degree in Business Administration with a concentration in Accounting from San Jose State University.

Aridis continues to present at leading investor and medical conferences. Recently, the Company participated at the 32nd Annual ROTH Conference on Monday, March 16th which was held on-line as a result of COVID-19.

Fiscal 2019 Fourth Quarter Results:

- **Cash**: Total cash and cash equivalents as of December 31, 2019 was $20.9 million.
- **Revenues:** Grant revenue decreased by approximately $567,000 from $1.6 million for the year ended December 31, 2018 to $1.0 million for the year ended December 31, 2019 primarily due to the completion and recognition of certain additional milestones related to the grant award from the CFF during 2018. There was no collaboration revenue in 2019. This is a decrease of approximately $1.2 million in collaboration revenue compared to 2018. All 2018 collaboration revenue was from the GSK collaboration arrangement which was terminated in December 2018. Revenue for the quarter ended December 31, 2019 was zero, a decrease of approximately $1.2 million in collaboration revenue and a decrease of approximately $222,000 in grant revenue compared to the same period

in 2018. Grant and collaboration revenues for the quarter decreased for the same reasons as for the full calendar year.

- **Research and Development Expenses:** Research and development expenses increased by approximately $1.1 million from $23.0 million for the year ended December 31, 2018 to $24.1 million for the year ended December 31, 2019. This was due primarily to an increase in spending on clinical trial activities and drug manufacturing for the Company's Phase 3 pivotal trial of AR-301, which was initiated in January 2019, and an increase in spending on the Phase 1/2a clinical trial of the AR-501 program, which was initiated in the fourth quarter of 2018, partially offset by a decrease in spending on clinical trial activities and drug manufacturing for the AR-105 program and a decrease in spending on toxicology studies related to the AR-501 program. Research and development expenses incurred in the quarter ended December 31, 2019 were $4.3 million, a decrease of approximately $1.3 million over the same period in 2018 due primarily to a decrease in spending on clinical trial activities and drug manufacturing for the AR-105 program, which was recently completed, partially offset by an increase in spending on clinical trial activities for both the AR-301 Phase 3 and the AR-501 Phase 1/2a programs.
- **General and Administrative Expenses:** General and administrative expenses increased by approximately $2.2 million from $3.9 million for the year ended December 31, 2018 to $6.0 million for the year ended December 31, 2019 due primarily to increases in professional service fees, directors' and officers' liabilities insurance expense, personnel related expenses, including stock-based compensation, and Delaware franchise taxes and patent related fees. There was no material difference in general and administrative expenses for the quarter ended December 31, 2019 when compared to the same period in 2018.
- **Interest and Other Income, net:** Interest and other income, net decreased by approximately $63,000 from $420,000 for the year ended December 31, 2018 to $357,000 for the year ended December 31, 2019. Interest and other income, net was $82,000 for the quarter ended December 31, 2019, a decrease of approximately $76,000 over the same period in 2018. These decreases were due primarily to 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 at the years ended December 31, 2019 and 2018. There was a $1.6 million gain attributed to a decrease in the fair value of the warrant liability during 2018 prior to our IPO in August 2018.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment increased by approximately $911,000 to $951,000 for the year ended December 31, 2019 from $40,000 over the same period in 2018, and increased by $22,000 to $41,000 for the quarter ended December 31, 2019 from $19,000 over the same period in 2018. These increases are due to the Company's share of loss from its minority interest calculated under the equity method.
- **Net Loss:** The net loss available to common stockholders for the year ended December 31, 2019 was $29.7 million, or ($3.51) per share, compared to a net loss available to common stockholders of $23.5 million, or ($7.45) per share, for the year ended December 31, 2018. The net loss available to common stockholders for the quarter ended December 31, 2019 was $5.6 million, or ($0.63) per share, compared to a net loss available to common stockholders of approximately $5.4 million, or ($0.67) per share, for the quarter ended December 31, 2018. It should be noted that there were 166,373 common shares outstanding during the first three quarters 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 stock was converted to common stock upon the completion of the IPO on August 16, 2018. As a result, the weighted average common shares outstanding for the full year 2018 was approximately 3.1 million. The weighted average common shares outstanding for the full year 2019 was approximately 8.5 million.

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 APEX™ 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 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 VAP and 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 (VAP). 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 VAP patients.

AR-101 (HAP). 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.

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 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.

Consolidated Balance Sheets

(in thousands)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 20,897	$ 24,237
Other current and noncurrent assets	7,070	7,374
Total Assets	$ 27,967	$ 31,611
Total Liabilities	$ 24,331	$ 5,297
Total stockholders' equity	3,636	26,314
Total liabilities and stockholders' equity	$ 27,967	$ 31,611

Aridis Pharmaceuticals, Inc.

Consolidated Statements of Operation

(in thousands, except share and per share amounts)

Three Months Ended December 31,		Twelve Months Ended December 31,	
2019	2018	2019	2018

Revenue	$ —	$ 1,391	$ 1,022	$ 2,757
Operating Expenses*				
Research and development	4,301	5,583	24,083	23,000
General and administrative	1,388	1,385	6,026	3,874
Total operating expenses	5,689	6,968	30,109	26,874
Loss from operations	(5,689)	(5,577)	(29,087)	(24,117)
Other income (expense)				
Interest and other income, net	82	158	357	420
Change in fair value of warrant liability	—	—	—	1,632
Share of loss from equity method investment	(41)	(19)	(951)	(40)
Net loss	$ (5,648)	$ (5,438)	$ (29,681)	$ (22,105)
Preferred dividends	$ —	$ —	$ —	$ (1,357)
Net loss available to common stockholders	$ (5,648)	$ (5,438)	$ (29,681)	$ (23,462)
Weighted-average common shares outstanding, basic and diluted	8,914,563	8,104,757	8,458,277	3,146,632
Net loss per share available to common stockholders, basic and diluted	$ (0.63)	$ (0.67)	$ (3.51)	$ (7.45)
*Includes stock based-compensation as follows				
Research and development	$ 123	$ 22	$ 662	$ 461
General and administrative	366	353	1,348	1,197
	$ 489	$ 375	$ 2,010	$ 1,658

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SOURCE Aridis Pharmaceuticals, Inc.
