Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Third Quarter 2019 Results

SAN JOSE, Calif., Nov. 13, 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 third quarter ended September 30, 2019.

Third Quarter Highlights and Recent Developments

- Advanced Phase 3 global clinical trial of AR-301 in patients with ventilator associated pneumonia (VAP) and remain on track to announce top line data expected in early 2021.
- Executed an equity purchase agreement with Serum Institute BV (SIBV), an affiliate of the Serum Institute of India, Ltd. (SIIL), whereby SIBV invested $10 million into Aridis.
- Executed license agreement with Serum AMR (SAMR), another affiliate of SIIL, for rights to multiple products and utilization of MabIgX® platform technology (transaction included a $15M upfront payment).
- Received Orphan Drug Designation (ODD) from The European Medicines Agency (EMA) for AR-501, an inhalable therapy for the treatment of chronic lung infections in cystic fibrosis patients.
- Continued enrolling AR-501's Phase 1/2a clinical trial with top-line data expected in Q1 2020 (healthy subjects), and in Q2 2021 (cystic fibrosis subjects).
- Enhanced leadership team with key appointments including infectious disease expert, Dr. Paul Mendelman as Interim Chief Medical Officer.
- Presented posters at the Infectious Disease Society of America's (IDSA) IDWeek™ 2019 on AR-105 and AR-501.
- Announced results from AR-105's global Phase 2 clinical trial for the treatment of VAP caused by *Pseudomonas aeruginosa (P. aeruginosa)*.

"The major emphasis for the period was laying the foundation for our long-term growth strategy as we head into the final quarter of 2019, and the new year. While we are certainly disappointed by AR-105's Phase 2 clinical trial result, our intense post-data analysis gives us conviction that the ongoing phase 3 study for AR-301 in *S. aureus* VAP is being conducted with utmost rigor and scrutiny incorporating lessons learned from AR-105 to bring this drug to market. Similarly, we remain confident in the design and execution of the ongoing phase 1/ 2 trial for AR-501 targeting infections in cystic fibrosis patients," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals.

"I'm especially pleased with the recent addition to management of Dr. Paul Mendelman who brings renowned infectious disease expertise to the team and is already impacting the data analysis of the AR-105 clinical trial as well as management of our ongoing Phase 3 clinical trial for AR-301 and Phase 1/2a clinical trial for AR-501 programs. Moving forward, we are now well positioned to execute on our clinical development strategy and to commence in earnest corporate development activities for the MabIgX® platform," continued Dr. Truong.

Clinical Program Update

AR-301: During the third quarter, Aridis continued enrolling its Phase 3 global clinical trial for AR-301, which targets gram-positive *S. aureus* in critically ill VAP patients. The trial, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 125 clinical centers in 20 countries. Interim data is expected in early 2020 and top line data is expected in early 2021. Participating centers in all countries are following 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 third 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 in Q1 2020 and the Phase 2a segment with cystic fibrosis subjects in Q2 2021.

AR-501, which is being developed in collaboration with the Cystic Fibrosis Foundation (CFF), has been granted by the U.S. Food and Drug Administration (FDA) both Fast Track and Qualified Infectious Disease Product Designation (QIDP) designations. 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.

AR-105: During the third quarter (September 3, 2019), Aridis reported results for its global Phase 2 clinical trial evaluating AR-105, a fully human IgG1 monoclonal antibody for the treatment of VAP caused by gram-negative *Pseudomonas aeruginosa (P. aeruginosa)*. The completed study did not meet its primary endpoint of demonstrating superiority in clinical cure rates on Day 21 compared to placebo. Furthermore, there was a statistically significant imbalance in all-cause mortality, as well as serious adverse event (SAE) rates between treatment groups that favored placebo. However, no SAE or mortality in the study was deemed to be drug related by the study investigators or the study's data monitoring committee. AR-105 has a different mechanism of action, directed at a different bacterium, and evaluated in a different patient population as compared to AR-301. While no further development resources will be allocated towards AR-105, the Company will continue to analyze the full data set to better understand the top-line results.

Throughout the third quarter, Aridis continued to attend investor and medical conferences and recently presented two posters at the Infectious Disease Society of America's (IDSA) IDWeek™ 2019, which took place on October 2nd-6th in Washington, DC. Both posters, "Pre-Clinical and Phase I Safety Data for Anti-*Pseudomonas aeruginosa* Human Monoclonal Antibody AR-105," and "In Vitro and In Vivo Non Clinical Efficacy of AR-501 (Gallium Citrate)," were presented on October 3, 2019.

Infectious Disease Specialist CMO Appointment: A recent key highlight occurred on October 11, 2019, when Aridis announced the appointment of Paul Mendelman, MD, as interim Chief Medical Officer, replacing Dr. Wolfgang Dummer who departed the company for personal reasons. 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. The Company also promoted Lynne Deans to the position of Vice President, Clinical Operations. Ms. Deans has over 30 years of experience in clinical operations and has held senior director of clinical operations positions in infectious diseases focused companies such as Cerexa, PaxVax, and Kalobios.

Corporate Update:

A key highlight during the third quarter was the execution of a license agreement with SAMR, an affiliate of SIIL. The agreement provides SAMR with the right to in-license Aridis' clinical stage programs AR-301(VAP), AR-105 (VAP) and AR-101 (hospital acquired pneumonia (HAP)). These license rights will be exclusive and to a limited territory which includes markets outside of the U.S., Europe, Canada, UK, China, Australia, New Zealand and Japan. Also, the agreement includes an exclusive, worldwide license (excluding China) to AR-201, a preclinical fully human mAb for the prevention of respiratory syncytial virus (RSV). In addition, SAMR may elect to collaborate with Aridis to utilize MabIgX® to identify and advance up to five SAMR wholly-owned programs. MabIgX® is Aridis' proprietary technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs.

Under the terms of the Agreement, Aridis received a $15M upfront payment and will be eligible to receive as much as $42.5 million in future milestone payments for achieving product development and commercial objectives, along with royalties on net sales. The consummation of this transaction follows an equity purchase agreement with SIBV, another affiliate of SIIL, which occurred in July 2019 whereby SIBV invested $10 million into Aridis.

"We continued to make major strides in corporate development with a key pharmaceutical alliance, which also improves our balance sheet. SIIL is the world's largest vaccine manufacturer by dose units and a significant monoclonal antibody development and manufacturing company. This combined product and technology license is a testament to the quality of our pipeline and groundbreaking MabIgX® platform for identifying rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs," concluded Dr. Truong.

Fiscal 2019 Third Quarter Results:

- **Cash**: Total cash and cash equivalents as of September 30, 2019 was $17.3 million. In addition, in October 2019 the Company received $10 million, the balance due on the upfront payment from SAMR upon the execution of license agreement referred to above.
- **Revenues:** Total revenues for the quarter ended September 2019 was zero, a decrease of $1.0 million over the same period in 2018 when a $1.0 million milestone payment was recognized from the CFF associated with its grant to fund the AR-501 Phase 1/2a clinical trial.
- **Research and Development Expenses:** Research and development expenses for the quarter ended September 30, 2019 were $6.0 million, a decrease of $0.9 million over the same period in 2018 due primarily to a decrease in spending on clinical trial activities and drug manufacturing for our AR-105 program, which was recently completed, partially offset by an increase in spending on clinical trial activities for both our AR-301 Phase 3 and the AR-501 Phase 1/2a programs.
- **General and Administrative Expenses:** General and administrative expenses for the quarter ended September 30, 2019 were $1.4 million, an increase of $0.6 million over the same period in 2018 due primarily to an increase in personnel related expenses, including stock-based compensation, an increase in patent related fees and an increase in directors' and officers' liabilities insurance expense.
- **Interest and Other Income, net:** Interest and other income, net for the quarter ended September 30, 2019 was $90,000, a decrease of $29,000 over the same period in 2018. This decrease was 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 end of the third quarter of 2019. There was a $1.4 million loss attributed to an increase in the fair value of the warrant liability in the third quarter of 2018.
- **Net Loss:** The net loss available to common shareholders for the quarter ended September 30, 2019 was $7.6 million, or ($0.87) per share, compared to a net loss available to common shareholders of $7.9 million, or ($1.97) per share, for the quarter ended September 30, 2018. It should be noted that there were 166,373 common shares outstanding during the third 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. As a result, the weighted average common shares outstanding for the third quarter of 2018 was 4.0 million. At September 30, 2019, the weighted average common shares outstanding for the third quarter of 2019 was 8.7 million.

About Aridis Pharmaceuticals, Inc.
Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives with mechanisms of action that are different from 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. 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 product candidates targeting bacteria that cause life-threatening infections such as VAP, HAP and chronic lung infections in cystic fibrosis. 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 as a chronic inhaled therapy 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-501 (cystic fibrosis). AR-501 is an inhaled formulation of gallium citrate with broad-spectrum anti-infective activity being developed as a chronic treatment for lung infections in cystic fibrosis patients. This program is currently in a Phase 1/2a clinical study in healthy volunteers and CF 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-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)

	September 30, 2019	**December 31, 2018**
	(unaudited)	
Cash and cash equivalents	$ 17,330	$ 24,237
Other current and noncurrent assets	17,037	7,374
Total Assets	$ 34,367	$ 31,611
Total Liabilities	$ 25,590	$ 5,297
Total stockholders' equity	8,777	26,314
Total liabilities and stockholders' equity	$ 34,367	$ 31,611

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended	**Nine Months Ended**

	September 30,		September 30,	
	2019	2018	2019	2018
	(unaudited)		*(unaudited)*	
Revenue	$ —	$ 1,022	$ 1,022	$ 1,367
Operating Expenses*				
Research and development	6,011	6,907	19,782	17,418
General and administrative	1,384	735	4,638	2,489
Total operating expenses	7,395	7,642	24,420	19,907
Loss from operations	(7,395)	(6,620)	(23,398)	(18,540)
Other income (expense)				
Interest and other income, net	90	119	275	262
Change in fair value of warrant liability	—	(1,388)	—	1,632
Equity in net loss from equity method investment	(282)	(20)	(910)	(20)
Net loss	$ (7,587)	$ (7,909)	$ (24,033)	$ (16,666)
Preferred dividends	$ -	$ (5)	$ -	$ (1,357)
Net loss available to common stockholders	$ (7,587)	$ (7,914)	$ (24,033)	$ (18,023)
Weighted-average common shares outstanding, basic and diluted	8,694,104	4,019,459	8,304,510	1,469,623
Net loss per common share, basic and diluted	$ (0.87)	$ (1.97)	$ (2.89)	$ (11.34)
Net loss per share available to common stockholders, basic and diluted	$ (0.87)	$ (1.97)	$ (2.89)	$ (12.26)
*Includes stock based-compensation as follows				
Research and development	$ 168	$ 159	$ 539	$ 439
General and administrative	351	235	900	745
	$ 519	$ 394	$ 1,439	$ 1,184

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