Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Third Quarter 2020 Results

SAN JOSE, Calif., Nov. 20, 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 infections, today reported financial and corporate results for the third quarter ended September 30, 2020.

Third Quarter Highlights and Recent Developments

- Announced positive preclinical efficacy data for AR-711, an inhaled, self-administered, at-home monoclonal antibody treatment ("mAb") for non-hospitalized mild-to-moderate COVID-19 patients. A clinical Phase 1/2 study is expected to be launched in 1H 2021.
- Received concurrence from the U.S. Food and Drug Administration ("FDA") to streamline AR-501's Phase 2 clinical trial design and to expand the originally planned Phase 2a protocol design into a Phase 2a/2b study for treating chronic lung infections in patients with cystic fibrosis (CF). Study completion is expected in 2H 2021.
- Continued enrolling global Phase 3 clinical trial of AR-301 in patients with ventilator associated pneumonia (VAP) including patients who presented with VAP secondary to ventilator placement for COVID-19. Interim futility analysis is expected in 1H 2021; full data is expected in YE 2021.
- Executed a Registered Direct offering with gross proceeds of approximately $8.5 million.
- Participated in leading healthcare dedicated investor forums.

"During the quarter and over the past few weeks, we achieved multiple important milestones that impact our clinical and corporate profile, highlighted by the addition of an inhaled at-home COVID-19 treatment (AR-711) to our portfolio of product candidates," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Additionally, we reached concurrence with the FDA to streamline and thus expedite the clinical and regulatory process for AR-501's Phase 2 program in cystic fibrosis, and bolstered our balance sheet with the $8.5 million financing. These important achievements have helped position us for continued growth as we head into the final quarter of the year."

COVID-19 Program Update

AR-711: During the quarter, Aridis announced the development of a highly potent fully human mAb against SARS-CoV-2 virus. AR-711 is designed to lower the barrier to treatment coverage of non-hospitalized COVID-19 patients by using a convenient, self-administered inhaled dosage presentation. AR-711 was discovered from convalescent COVID-19 patients and targets the conserved receptor-binding domain (RBD) region of the spike protein of the original SARS-CoV2 virus and its newly emerging variants including the currently prevalent strain G614. AR-711 exhibits high affinity for the SARS-CoV-2 virus, approximately 10-fold or higher than mAb candidates currently in late stage clinical testing.

In an animal challenge study with golden Syrian hamsters, inhaled AR-711 successfully eliminated all detectable SARS-CoV-2 virus at substantially lower doses than parenterally administered (injected) COVID-19 mAb. AR-711 is engineered to be long-acting in blood for up to six to twelve months and is stabilized using a proprietary formulation designed to protect the mAb from the physical stresses imparted by commercial nebulizer delivery devices on protein drugs. The potency of AR-711 and its direct delivery to the lungs by inhaled administration may facilitate significant dose sparing not achievable by parenteral administration. A proprietary formulation enables AR-711 to be deliverable using a variety of commercially available nebulizers that can be self-administered on an outpatient basis, thus lowering the barrier to COVID-19 therapeutic treatment. Clinical trials for AR-711 are expected to commence 1H 2021.

AR-701: With the goal of treating COVID-19 patients at home with inhaled AR-711 and in the hospital with intravenous AR-701 mAb cocktail, during the quarter, Aridis continued to characterize this cocktail of fully human mAbs discovered from the Company's in-house ΛPEX^{TM} mAb discovery platform that are directed at multiple envelope proteins of the SARS-CoV-2 virus.

Clinical Program Update

AR-301: Thus far, the pace of the trial has been modestly impacted by the protracted COVID-19 pandemic. The Phase 3 interim futility analysis from the ongoing pivotal trial is now expected to be reported in 1H 2021 and top line data by YE 2021. It's important to note that COVID-19 patients on prolonged mechanical ventilation in the intensive care unit (ICU) are prone to secondary infections (also called 'superinfections') by opportunistic pathogens such as bacteria. Superinfection is a reported complication in COVID-19 patients, which exacerbates morbidity and the rate of mortality. The AR-301 Phase 3 study allows for the enrollment of patients with

baseline characteristics which are inclusive of certain COVID-19 patients. While AR-301 is not an agent to treat SARS-CoV-2 virus itself, it can potentially reduce the morbidity associated with secondary *S. aureus* pneumonia, which is a coronavirus complication and a contributing cause of death in such patients.

The trial, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 160 clinical centers in 22 countries. Participating clinical centers that are activated continue to follow standard stringent clinical protocols and procedures for critically ill VAP patients, as is standard in the U.S. and Europe. The trial represents one of 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 quarter, the Company announced an agreement with the FDA to simplify AR-501's Phase 2 trial design for the treatment of chronic lung infections associated with cystic fibrosis (CF). After reporting (June 2020) positive Phase 1 safety data in healthy adults who were exposed to a single ascending dose (SAD) or a multiple ascending dose (MAD) regimen, Aridis proposed, and the FDA has now agreed, to streamline AR-501's forthcoming Phase 2a clinical trial in CF patients by removing the SAD and only conducting a MAD regimen. The FDA also concurred with the Company's proposal to expand the originally planned Phase 2a protocol design into a Phase 2a/2b study. This Phase 2a/2b design will enable seamless and efficient advancement of the study from Phase 2a into Phase 2b using the same clinical study protocol. The data from the Phase 2a will inform the dose selection and sample size expansion to achieve statistical significance in efficacy in Phase 2b.

AR-501 is being developed in collaboration with the CF Foundation and has been granted Orphan Drug Designation (ODD), Fast Track and Qualified Infectious Disease Product (QIDP) designations by the FDA. In addition, the European Medicines Agency (EMA) granted ODD to AR-501. The original Phase 1/2a clinical trial was a randomized, double-blinded, placebo-controlled SAD and MAD trial investigating the safety and PK of inhaled AR-501 in healthy volunteers and cystic fibrosis patients with chronic bacterial lung infections. Details of the original Phase 1/2a clinical trial can be viewed on www.clinicaltrials.gov using identifier NCT03669614. The new Phase 2a/b study design will be available on clinicaltrials.gov within the next quarter.

Corporate Update

A key recent development was the closing of an $8.5 million financing which occurred on October 14th. The proceeds from this registered direct offering and concurrent private placement, strengthens the Company's balance sheet to prioritize the continued advancement of AR-301's Phase 3 VAP clinical trial, while allocating the requisite resources to AR-501's Phase 2b cystic fibrosis clinical trial, and the ongoing development of novel COVID-19 therapies such as AR-701 and AR-711.

Throughout the third quarter, Aridis continued to increase its profile in the investment and business communities by participating in the 2020 Cantor Fitzgerald Virtual Global Healthcare Conference and the H.C. Wainwright 22nd Annual Global Investment Conference on September 15, 2020.

A replay of the Cantor Fitzgerald event can be found at https://investors.aridispharma.com/events.

Fiscal 2020 Third Quarter Results:

- **Cash**: Total cash and cash equivalents as of September 30, 2020 was $6.2 million. The Company completed a registered direct financing in October 2020 and received gross proceeds of approximately $8.5 million.
- **Revenues:** Revenue was zero for both periods ended September 30, 2020 and 2019.
- **Research and Development Expenses:** Research and development expenses incurred in the quarter ended September 30, 2020 were approximately $4.2 million, a decrease of approximately $1.8 million over the same period in 2019. The decrease was primarily due to the following: a decrease in spending on clinical trial activities and drug manufacturing expenses for the Phase 2 study of our AR-105 program, that was terminated during 2019; a decrease in spending on our clinical trial activities for the Phase 3 study of our AR-301 program during the third quarter of 2020 as compared to the third quarter of 2019, which included increased study start-up costs; and a decrease in spending on clinical trial activities for the Phase 1/2a study of our AR-501 program because the Phase 1 portion of the study ended in the second quarter of 2020. These decreases were partially offset by an increase in drug manufacturing related expenses for the Phase 3 study of our AR-301 program during the third quarter of 2020 as compared to the third quarter of

2019.

- **General and Administrative Expenses:** General and administrative expenses incurred in the quarter ended September 30, 2020 were approximately $1.6 million, an increase of approximately $247,000 over the same period in 2019 which was due primarily to increases in professional service fees, directors' and officers' related liabilities insurance expense, personnel related expenses, including stock-based compensation, patent related fees, and Delaware franchise taxes.
- **Interest Income, net:** Interest income, net was approximately $6,000 for the quarter ended September 30, 2020, a decrease of approximately $84,000 over the same period in 2019. This decrease was primarily due to lower cash balances and lower interest rates during the third quarter of 2020 as compared to the third quarter of 2019.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment decreased by $282,000 for the quarter ended September 30, 2020 when compared to the same period in 2019 which was due to there being no share of losses from our equity method investment recorded in the third quarter of 2020 as the net book value of the investment was zero since March 31, 2020.
- **Net Loss:** The net loss for the quarter ended September 30, 2020 was approximately $5.8 million, or $0.65 net loss per share, compared to a net loss of approximately $7.6 million, or $0.87 net loss per share, for the quarter ended September 30, 2019. The weighted average common shares outstanding was approximately 8.9 million and approximately 8.7 million for the third quarter of 2020 and 2019, respectively.

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 ΛPEX™ 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 monoclonal antibody (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 technically 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 ventilator associated pneumonia (VAP) and hospital acquired pneumonia (HAP), in addition to preclinical stage antibacterial and antiviral mAbs. 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 IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *Staphylococcus aureus* (*S. aureus)* alpha-toxin in VAP patients.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* (*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-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that are directed at multiple envelope proteins of the SARS-CoV-2 virus.

AR-711 (COVID-19). AR-711 is a fully human IgG1 mAb that is directed against the receptor binding domain of the SARS-Cov 2 virus. AR-711 is being developed to treat non-hospitalized mild to moderate COVID-19 patients by inhalation using a nebulizer.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb out-licensed 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 need for additional financing, 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.

Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2020	December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 6,212	$ 20,897
Other current and noncurrent assets	5,894	7,070
Total Assets	$ 12,106	$ 27,967
Total Liabilities	$ 23,404	$ 24,331
Total stockholders' equity (deficit)	(11,298)	3,636
Total liabilities and stockholders' equity (deficit)	$ 12,106	$ 27,967

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,	
	2020	2019	2020	2019
	(unaudited)		*(unaudited)*	

Revenue	$ —	$ —	$ 1,000	$ 1,022
Operating Expenses*				
Research and development	4,161	6,011	12,725	19,782
General and administrative	1,631	1,384	4,853	4,638
Total operating expenses	5,792	7,395	17,578	24,420
Loss from operations	(5,792)	(7,395)	(16,578)	(23,398)
Other income (expense)				
Interest income, net	6	90	77	275
Share of loss from equity method investment	—	(282)	(9)	(910)
Net loss	$ (5,786)	$ (7,587)	$ (16,510)	$ (24,033)
Weighted-average common shares outstanding, basic and diluted	8,923,374	8,694,104	8,922,052	8,304,510
Net loss per share, basic and diluted	$ (0.65)	$ (0.87)	$ (1.85)	$ (2.89)
*Includes stock based-compensation as follows:				
Research and development	$ 156	$ 168	$ 431	$ 539
General and administrative	406	367	1,131	982
	$ 562	$ 535	$ 1,562	$ 1,521

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