Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces First Quarter 2020 Results

SAN JOSE, Calif., May 12, 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 first quarter ended March 31, 2020.

First Quarter Highlights and Recent Developments

- Enrolled the first patient with COVID-19 in AR-301 Phase 3 trial for patients with ventilator associated pneumonia (VAP)
- Initiated dosing of the last dose cohort in the healthy volunteer portion of the AR-501 Phase 1/2a clinical trial with top-line data provisionally expected in 1H 2020 (healthy subjects), and in 2H 2021 (cystic fibrosis subjects)
- Commenced COVID-19 monoclonal antibody and vaccine discovery activities utilizing the APEX™ platform technology

"While the COVID-19 pandemic has provided significant headwinds to patient trial enrollment across therapeutic indications including our own ongoing studies, we were still able to advance our lead programs and in fact, enrolled our first patient diagnosed with COVID-19 and on a ventilator into the AR-301 Phase 3 VAP study," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Furthermore, the pandemic provided a unique opportunity to leverage our APEX platform technology for the rapid discovery and development of highly potent monoclonal antibodies from convalescent COVID-19 patients."

During the quarter, Aridis initiated COVID-19 monoclonal antibody and vaccine discovery activities utilizing its APEX™ technology platform for the unbiased discovery of new and highly potent antibodies against pathogens. The APEX™ platform is comprised of a silicon wafer-based array of nanoliter sized tissue micro-culture wells that enable rapid screening of antibody secreting cells, enabling discovery of potent antibodies against targets such as the virus that causes COVID-19 disease (called 'SARS-CoV-2') within a few days of patient sample availability. It also features CRISPR enabled activation of endogenous genetic control elements that dramatically increase the yield of bio-therapeutic drugs from manufacturing production cell lines. The technology also features a proprietary production cell line that is designed to rapidly manufacture multiple monoclonal antibody therapeutics at approximately half the manufacturing cycle time than currently available manufacturing technologies.

Clinical Program Update

AR-301: In April, Aridis enrolled its first COVID-19 patient in the Company's ongoing Phase 3 clinical trial of AR-301. 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 rate of mortality. The Company's ongoing 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. However, the advent of coronavirus infections which became apparent during the fourth quarter of 2019, impacted 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. Contingent upon the evolution 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 first quarter, Aridis initiated dosing of the last dose cohort in healthy volunteer portion of the AR-501 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 Orphan Drug Designation (ODD), Fast Track and Qualified Infectious Disease Product (QIDP) designations by the U.S. Food and Drug Administration (FDA). In addition, the European Medicines Agency (EMA) granted ODD to AR-501. 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 first quarter, Aridis continued to present at leading investor and medical conferences, which due to the COVID-19 pandemic have been transitioned to virtual forums. The Company participated in Maxim Group's Infectious Disease Virtual Conference held on May 5, 2020. The event consisted of four panels of companies in various stages of development, from early stage to near commercialization, that represent the next wave of innovation in the infectious disease sector. Vu Truong, Ph.D., Aridis' Chief Executive Officer, was a speaker on two panels entitled "Non-antibiotic Anti-infectives" and "COVID-19 (Therapeutics)." The presentation slides can be found at https://investors.aridispharma.com/publications-and-posters.

Fiscal 2020 First Quarter Results:

- **Cash**: Total cash and cash equivalents as of March 31, 2020 was $16.3 million.
- **Revenues:** Grant revenue decreased from approximately $1.0 million for the quarter ended March 31, 2019 to zero for the quarter ended March 31, 2020 primarily due to the recognition of revenue related to a milestone under the grant award from the CFF during the first quarter of 2019 and none during the first quarter of 2020.
- **Research and Development Expenses:** Research and development expenses incurred in the quarter ended March 31, 2020 were $4.9 million, a decrease of approximately $2.2 million over the same period in 2019 due primarily to a decrease in spending on clinical trial activities for the AR-105 Phase 2 program, which was completed in 2019, and a decrease in drug manufacturing expenses related to the AR-301 Phase 3 program. These decreases were 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:** There was no material difference in general and administrative expenses for the quarter ended March 31, 2020 when compared to the same period in 2019.
- **Interest and Other Income, net:** Interest and other income, net was $61,000 for the quarter ended March 31, 2020, a decrease of approximately $55,000 over the same period in 2019. These decreases were due primarily to a lower average cash balance and lower interest rates.
- **Share of Loss from Equity Method Investment:** Loss from equity method investment decreased by $433,000 to $9,000 for the quarter ended March 31, 2020 over the same period in 2019 due to our share of loss from our minority interest under the equity method was limited to the book value of the investment.
- **Net Loss:** The net loss for the quarter ended March 31, 2020 was $6.5 million, or ($0.73) per share, compared to a net loss of approximately $8.1 million, or ($0.99) per share, for the quarter ended March 31, 2019. The weighted average common shares outstanding was approximately 8.9 million and approximately 8.1 million for the first 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 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 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 (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 in Phase 2 clinical development 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 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 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)

	March 31, 2020	December 31, 2019
	(unaudited)	
Cash and cash equivalents	$ 16,324	$ 20,897
Other current and noncurrent assets	5,683	7,070
Total Assets	$ 22,007	$ 27,967

Total Liabilities	$ 24,384	$ 24,331
Total stockholders' equity (deficit)	(2,377)	3,636
Total liabilities and stockholders' equity (deficit)	$ 22,007	$ 27,967

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
	(unaudited)	
Revenue	$ —	$ 1,022
Operating Expenses*		
Research and development	4,917	7,118
General and administrative	1,639	1,641
Total operating expenses	6,556	8,759
Loss from operations	(6,556)	(7,737)
Other income (expense)		
Interest and other income, net	61	116
Share of loss from equity method investment	(9)	(442)
Net loss	$ (6,504)	$ (8,063)
Weighted-average common shares outstanding, basic and diluted	8,919,393	8,105,636
Net loss per share, basic and diluted	$ (0.73)	$ (0.99)
*Includes stock based-compensation as follows		
Research and development	$ 145	$ 173
General and administrative	332	277
	$ 477	$ 450

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