Aridis Pharmaceuticals Announces First Quarter 2023 Financial Results and Business Update

LOS GATOS, Calif., June 8, 2023 (GLOBE NEWSWIRE) -- Aridis Pharmaceuticals, Inc. (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of novel anti-infective therapies for treating life-threatening infections, today reported financial and corporate results for its first quarter ended March 31, 2023.

First Quarter & Subsequent Highlights

- Met primary safety and secondary pharmacokinetics endpoints in AR-501 Phase 2a study in cystic fibrosis (CF). CF patients achieved high uptake of AR-501 in the respiratory tract at levels that were more than 50-fold higher than required for inhibition of the target bacteria *P. aeruginosa.* The study was conducted with funding support from the Cystic Fibrosis Foundation.
- Reported positive results from the first Phase 3 study of AR-301 in mechanically ventilated hospitalized patients, especially in the prespecified older adult population of 65+ years. The absolute efficacy in the AR-301-002 Phase 3 study was higher in older adults than the overall population, i.e., +34% improvement on Day 21 (p= 0.057) and +38% on Day 28 (p= 0.025) in older adults versus +11% improvement (p=0.24) in the overall population on both Days.
- Received positive feedback from the US Food and Drug Administration (FDA) on the Company's proposed single confirmatory Phase 3 study of AR-301 to support the submission of a Biologics License Application (BLA). The FDA agreed to the proposed expansion of the confirmatory Phase 3 study in *S. aureus* ventilator associated pneumonia (VAP) patients to include ventilated hospital acquired pneumonia (HAP) and ventilated community acquired pneumonia (CAP) patients.
- Raised gross proceeds of $2.28 million through a registered direct offering of 6,000,000 shares of common stock at a purchase price of $0.38 per share.

"Our first quarter results demonstrate the continued progress and momentum of Aridis Pharmaceuticals. We are pleased that both primary and secondary endpoints in the AR-501 Phase 2a study have been met," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals.

Dr. Truong continued, "The positive results from our first Phase 3 study of AR-301 in the older adult population are particularly encouraging, as this is a group that typically experiences lower efficacy with standard antibiotic treatments. Our focus on improving clinical cure rates for this vulnerable population is consistent with our commitment to address unmet medical needs. The Company has advanced its clinical programs AR-301, AR-320, and AR-501 to a mature stage of development, and our efforts will be focused on realizing the value to our shareholders in the near future."

Regarding the FDA's feedback, Dr. Truong stated, "We are extremely pleased with the positive response we received from the FDA regarding our proposed single confirmatory Phase 3 study of AR-301. This development will allow us to expand our study to include patients with ventilator-associated pneumonia, hospital-acquired pneumonia, and community-acquired pneumonia, further demonstrating the potential impact of this innovative therapy."

Clinical Programs Update

AR-301 (tosatoxumab): AR-301 is being evaluated as an adjunctive treatment to standard of care antibiotics in *Staphylococcus aureus* (*S. aureus*) mechanically ventilated hospitalized patients. The recently completed trial of AR-301 represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human mAb to treat acute pneumonia in the intensive care unit (ICU) setting. Aridis received positive feedback from the FDA on the Company's proposed single confirmatory Phase 3 study of AR-301. The FDA agreed on the design of the single confirmatory Phase 3 superiority study required to support the submission of a Biologics License Application (BLA) and agreed to the proposed expansion of the confirmatory Phase 3 study in S. aureus ventilator associated pneumonia (VAP) patients to include ventilated hospital acquired pneumonia (HAP) and ventilated community acquired pneumonia (CAP) patients. Details of the first Phase 3 study can be viewed at www.clinicaltrials.gov using identifier NCT03816956.

AR-501 (gallium citrate): AR-501 is being developed in collaboration with and with funding support from the Cystic Fibrosis Foundation. In March, Aridis announced preliminary top-line results from the randomized, double blinded, placebo-controlled Phase 2a study of AR-501, which evaluated the safety and pharmacokinetics of three ascending doses of AR-501 administered as an inhaled aerosol in cystic fibrosis (CF) patients with confirmed Pseudomonas aeruginosa bacterial and other potential infections; the study's primary and secondary endpoints of safety and pharmacokinetics (PK) were met. Key findings of the study include: CF patients achieved high uptake of AR-501 in the respiratory tract, as measured by sputum concentrations, at levels that were more than 50-fold higher than required for inhibition of the target bacteria *P. aeruginosa*; inhaled delivery achieved more than 10-fold higher respiratory uptake of gallium (AR-501) than past clinical studies of intravenous (IV) gallium which resulted in lung function improvement and P. aeruginosa reduction. Details of the Phase 1 / 2a clinical trial can be viewed at https://www.clinicaltrials.gov using identifier NCT03669614.

AR-320 (suvratoxumab): AR-320 is a fully human immunoglobulin G1 (IgG1) monoclonal antibody (mAb) targeting *S. aureus* alpha toxin being developed as a preemptive treatment of mechanically ventilated ICU patients who are colonized with *S. aureus* but do not yet have VAP. AR-320 is active against infections caused by both methicillin resistant *S. aureus* (MRSA) and methicillin sensitive *S. aureus* (MSSA). A multinational, randomized, double-blind, placebo-controlled Phase 2 study (n=196 patients) showed that mechanically ventilated ICU patients colonized with *S. aureus* who were treated with suvratoxumab demonstrated a relative risk reduction in onset of pneumonia by 32% in the overall intent-to-treat study population, and by a statistically significant 47% relative risk reduction in the under 65-year-old population, which is the target population in the planned Phase 3 study. This risk reduction in the target population was also associated with a substantial reduction in the duration of care needed in the ICU and the hospital. This program is currently placed on temporary clinical hold while the Company discusses potential resolutions with AstraZeneca on the commercial license.

First Quarter 2023 Financial Results:

- **Cash**: Total cash, cash equivalents and restricted cash as of March 31, 2023, were approximately $1.8 million.

- **Revenues:** Grant and licensing revenue was approximately $1.1 million for the quarter ended March 31, 2023 primarily due to the recognition of revenue from grants from the Cystic Fibrosis Foundation (CFF) and the Gates Foundation as well as from Kermode, an Apex technology licensee. Grant and licensing revenue earned during the quarter ended March 31, 2022 was approximately $3.1 million, from CFF, Gates and Kermode.

- **Research and Development Expenses:** Research and development expenses decreased by approximately $0.9 million to $5.5 million for the quarter ended March 31, 2023 from $6.4 million for the quarter ended March 31, 2022. The decrease was due primarily to a decrease of approximately $819,000 for manufacturing of clinical supplies for the initiation of a Phase 1 clinical trial evaluating AR-701 for the treatment of COVID-19; a decrease of approximately $706,000 in spending on our clinical trial evaluating AR-320 for the prevention of VAP; offset by an increase of approximately $250,000 in spending on our ongoing Phase 2a clinical trial evaluating AR-501 for the treatment of cystic fibrosis; and an increase of approximately $318,000 in spending on completion and normal wind-down costs for our Phase 3 clinical trial evaluating AR-301 for the treatment of VAP.

- **General and Administrative Expenses:** General and administrative expenses decreased by approximately $0.3 million to $1.8 million for the quarter ended March 31, 2023 from $2.2 million for the quarter ended March 31, 2022. The decrease was due primarily to decreases in stock compensation expense, professional fees and liability insurance, partially offset by an increase in personnel related costs and DE franchise tax.

- **Interest (Expense) Income net:** Net interest expense increased by approximately $275,000 to approximately $27,000 for the quarter ended March 31, 2023 from approximately $248,000 net interest income for the same quarter in the prior year.

- **Other Income:** Other income increased by approximately $3,000 to approximately $25,000 for the quarter ended March 31, 2023, from $22,000 for the quarter ended March 31, 2022.

- **Change in Fair Value of Note Payable:** Change in fair value of notes payable decreased by approximately $489,000 to $(605,000) for the quarter ended March 31, 2023 from $(116,000) for the quarter ended March 31, 2022.

- **Net Loss:** The net loss for the quarter ended March 31, 2023, was approximately $6.8 million, or $0.22 net loss per share, compared to a net loss of approximately $7.8 million, or $0.44 net loss per share, for the quarter ended March 31, 2022. The weighted average common shares

outstanding used in computing net loss per share was 30,414,865 and 17,701,592 for the quarter ended March 31, 2023 and 2022, respectively.

- **Change in Other Comprehensive Income:** Change in other comprehensive income increased by approximately $861,000 for the quarter ended March 31, 2023 from $0 for the quarter ended March 31, 2022.

About Aridis Pharmaceuticals, Inc.
Aridis Pharmaceuticals, Inc. discovers and develops anti-infectives to be used as first-line treatments to combat antimicrobial resistance (AMR) and viral pandemics. 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 mAbs for therapeutic treatment of critical infections. These mAbs are already of human origin and functionally optimized by the natural human immune system for high potency. Hence, they are already fit-for-purpose and do not require further engineering 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 *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 to treat chronic lung infections in cystic fibrosis patients. This program is currently in a Phase 2a clinical study in CF patients.

AR-320 (VAP). AR-320 is a fully human mAb targeting *S. aureus* alpha-toxin for prevention of VAP. Statistically significant Phase 2 data in the target population of those ≤ 65 years of age was published in the September 2021 Lancet Infectious Diseases journal.

AR-701 (COVID-19). AR-701 is a cocktail of fully human mAbs discovered from convalescent COVID-19 patients that target multiple sites on the spike proteins of the SARS-CoV-2 virus.

AR-101 (HAP). AR-101 is a fully human IgM mAb in Phase 2 clinical development targeting *Pseudomonas aeruginosa* liposaccharides serotype O11, which accounts for approximately

22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide. This program is licensed to the Serum Institute of India and Shenzhen Arimab.

AR-201 (RSV infection). AR-201 is a fully human IgG1 mAb directed against the F-protein of diverse clinical isolates of respiratory syncytial virus (RSV). This program is licensed exclusively to the Serum Institute of India.

AR-401 (blood stream infections). AR-401 is a fully human mAb preclinical program aimed at treating infections caused by gram-negative *Acinetobacter baumannii*.

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, 2022, 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, 2023	December 31, 2022
	(unaudited)	

Cash and cash equivalents	$ 1,320	$ 4,876
Other current and noncurrent assets	8,114	9,819
Total assets	$ 9,434	$ 14,695
Total liabilities	$ 37,316	$ 38,927
Total stockholders' deficit	(27,881)	(24,232)
Total liabilities and stockholders' deficit	$ 9,434	$ 14,695

Aridis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
	(unaudited)	
Revenue	$ 1,082	$ 1,187
Operating expenses:		
Research and development	5,531	6,450
General and administrative	1,814	2,161
Total operating expenses	7,345	8,611
Loss from operations	(6,263)	(7,424)
Other income (expense):		
Interest (expense) income, net	27	(248)
Other income, net	25	22
Change in fair value of note payable	(605)	(116)
Net loss	$ (6,816)	$ (7,766)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted	30,414,865	17,701,592
Net loss per share to common stockholders, basic and diluted	$ (0.22)	$ (0.44)
Net loss	$ (6,816)	$ (7,766)
Other comprehensive income	$ 861	—
Total comprehensive (loss) income	$ (5,955)	$ (7,766)
*Includes stock based compensation as follows		
Research and development	$ 144	$ 166
General and administrative	101	301
	$ 245	$ 467

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