Aridis Pharmaceuticals Announces Third Quarter 2023 Financial Results and Business Update

Received two grant awards from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health

LOS GATOS, Calif., November 3, 2023 (Globe Newswire) -- Aridis Pharmaceuticals, Inc. (OTCQB: 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 third quarter ended September 30, 2023.

Third Quarter Highlights

- Received a grant award from the National Institute of Allergy and Infectious Diseases (NIAID) division of the National Institutes of Health (NIH), in collaboration with researchers at Eitr Biologics in San Diego, California, to develop pan-coronavirus human monoclonal antibody ('mAb').
- Received a grant award from NIAID in collaboration with researchers at Emory University in Atlanta, Georgia, to apply the Company's APEX™ human mAb discovery and production platform technology to discover and develop antibacterial mAbs from patients.
- Positive non-human primate efficacy data from the Company's COVID-19 mAb program AR-701 was accepted for publication in the peer reviewed scientific journal *Nature Communications*. AR-701 mAbs exhibit broad pan-coronavirus neutralization activity, including recent Omicron variants.
- The Company has been uplisted to the OTCQB market, joining over 900 other companies that are currently on this market. OTCQB companies must be current in their financial reporting and undergo an annual verification and management certification process.
- Raised gross proceeds of $2.0 million through issuance and sale of approximately 10 million shares of common stock and common stock equivalents at market price and approximately 10 million common stock warrants.

"With multiple late clinical stage assets and a strong platform technology, our company has been actively pursuing partnering discussions to maximize the value of these assets for our shareholders. We remain optimistic of successful outcomes from these efforts in the coming months," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Continuing our long-standing history of procurement of non-dilutive grant funding, we are pleased to announce multiple NIH grants that we expect will begin funding in the fourth quarter."

Clinical Programs Update

AR-501 (gallium citrate): AR-501 is being developed in collaboration with and with funding support from the Cystic Fibrosis Foundation. Aridis reported preliminary top-line results from the randomized, double blinded, placebo-controlled Phase 2a study of AR-501, that 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 *Pseudomonas 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. The safety margin was further expanded by evaluating a higher dose cohort of 80mg comprising of 6 CF subjects. The independent Data Safety Monitoring Board (DSMB) also did not express any safety concerns at the 80mg dose level and agreed with the ongoing development of the product. 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 monoclonal antibody (mAb) targeting *Staphylococcus 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 ventilator-associated pneumonia (VAP). This program is currently placed on temporary clinical hold while the Company discusses potential resolution with AstraZeneca on the commercial license.

AR-301 (tosatoxumab): AR-301 is an anti-*S. aureus* mAb with similar target and mechanism of action as AR-320 but being developed as an adjunctive therapeutic treatment of ICU patients with VAP caused by *S. aureus*. Top-line data from the first of two Phase 3 superiority clinical studies showed strong clinical and pharmacoeconomic benefit trends in patients treated with AR-301, especially in the prespecified older adults (65+ years) patients. Aridis received concurrence from the FDA (U.S. Food Drug Administration) and EMA (European Medicines Agency) on the Company's proposed single confirmatory Phase 3 study, study endpoints, and patient populations. AR-301 received Priority Review status from the Qualified Infectious Disease Designation (QIDP) and was deemed eligible for consideration under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). The Company is in active discussions with potential pharmaceutical partners and investors to advance the program toward the confirmatory Phase 3 trial and BLA application.

Third Quarter Financial Results:

- **Cash**: Total cash, cash equivalents and restricted cash as of September 30, 2023, were approximately $0.5 million.

- **Revenues:** Grant revenue was approximately $0.4 million for the quarter ended September 30, 2023, primarily due to the recognition of revenue from a grant from the Cystic Fibrosis Foundation. A total of $0.4 million in grant revenue was reported for the quarter ended September 30, 2022.

- **Research and Development Expenses:** Research and development expenses decreased by approximately $5.9 million, from approximately $6.1 million for the quarter ended September

30, 2022, to approximately $0.2 million for the quarter ended September 30, 2023. The decrease was primarily due to decreases in spending associated with our paused clinical trials for AR-320 and AR-301 and reduced clinical trial activities for AR-501 and our COVID-19 programs.

- **General and Administrative Expenses:** General and administrative expenses decreased to approximately $1.1 million for the three months ended September 30, 2023, from approximately $1.7 million for the three months ended September 30, 2022. Headcount reductions contributed to decreases in salaries and wages and related benefit expenses.

- **Interest Income (Expense) net:** Net interest income was approximately $1,000 for the quarter ended September 30, 2023, compared to approximately $27,000 interest expense for the quarter ended September 30, 2022. Due to fair value option valuation of our notes payable, there was no interest expense recorded during the third quarter of 2023.

- **Other Income:** Other income increased to $26,000 for the quarter ended September 30, 2023, compared to approximately $23,000 for the quarter ended September 30, 2022. The income was primarily due to a sublease agreement we entered into with a tenant in March 2021 for a small portion of our Los Gatos facility.

- **Common Stock:** During the three-month period ended September 30, 2023, a total of 8,496,489 shares were issued resulting in common stock outstanding of 44.6 million shares.

- **Net Loss:** The net loss available to common stockholders for the quarter ended September 30, 2023, was approximately $83,000, a $0.00 net loss per share, compared to a net loss available to common stockholders of approximately $8.2 million or $0.47 net loss per share for the quarter ended September 30, 2022. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was approximately 37.4 million and approximately 17.7 million for the third quarter of 2023 and 2022, respectively.

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/HAP/CAP). AR-301 is a fully human IgG1 mAb currently in Phase 3 clinical development targeting gram-positive *S. aureus* alpha-toxin in ventilator associated pneumonia (VAP), ventilated hospital acquired pneumonia (HAP), and ventilated community acquired pneumonia (CAP) 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. The Company has completed discussions with the EMA and FDA on study design and recently launched the Phase 3 study.

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* HAP 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
Cash and cash equivalents	$ 35	$ 4,876
Other current and noncurrent assets	6,499	9,819
Total assets	$ 6,534	$ 14,695
Total liabilities	$ 18,336	$ 38,927
Total stockholders' deficit	(11,802)	(24,232)
Total liabilities and stockholders’ deficit	$ 6,534	$ 14,695

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,	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
Revenue:				
Grant revenue	$ 417	$ 399	$ 1,544	$ 1,878
License revenue	—	—	19,602	—
Total revenue	417	399	21,146	1,878
Operating expenses:				
Research and development	175	6,118	10,374	18,916
General and administrative	1,111	1,693	4,235	5,535
Total operating expenses	1,286	7,811	14,609	24,451
Loss from operations	(869)	(7,412)	6,537	(22,573)
Other income (expense):				
Interest income (expense), net	1	(27)	31	(267)
Other income	26	23	77	68
Change in fair value of note payable	759	(823)	(1,400)	(1,212)
Net loss	$ (83)	$ (8,239)	$ 5,245	$ (23,984)
Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted				
Basic	37,428,943	17,701,592	35,562,129	7,701,592
Diluted	37,428,943	17,701,592	47,178,967	7,701,592
Earnings (net loss) per share:				
Basic	$ 0.00	$ (0.47)	$ 0.15	$ (1.35)
Diluted	$ 0.00	$ (0.47)	$ 0.11	$ (1.35)
Net loss	$ (83)	$ (8,239)	$ 5,245	$ (23,984)
Other comprehensive income	1,261	—	2,736	—
Total comprehensive income (loss)	$ 1,178	$ (8,239)	$ 7,981	$ (23,984)

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