Aridis Pharmaceuticals

# Aridis Pharmaceuticals Announces Third Quarter 2021 Results

## Executed AstraZeneca in-licensing deal of Phase 3-ready antibody, suvratoxumab, in July 2021
## Bolstered financial position with approx. $25 million in equity financing in August 2021

LOS GATOS, Calif., Nov. 10, 2021 /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 its third quarter ended September 30, 2021.

**Third Quarter Highlights**

- Executed an agreement with AstraZeneca, in-licensing the Phase 3-ready monoclonal antibody (mAb) candidate, suvratoxumab (AR-320), being evaluated for the prevention of pneumonia and supported by positive Phase 2 data, published in The Lancet Infectious Diseases journal, showing a relative risk reduction of pneumonia of 32% in the overall intent to treat study population and a statistically significant relative risk reduction of 47% in the target population of the Company's planned Phase 3 study. In connection with this agreement, there was a one-time expense of $11.5 million, $6.5 million of which is attributed to the non-cash issuance of common shares.
- AstraZeneca took an equity stake in Aridis as part of the agreement. The launch of the Phase 3 study is expected in early 2022 and will be supported by up to €25.0 million (approximately $30.0 million) of funding from the EU Commission's Innovative Medicines Initiatives (IMI), remains on track.
- Aridis believes that AR-320, if approved, will be a first line, first-to-market, first-in-class pre-emptive treatment of *Staphylococcus aureus (S. aureus)* colonized patients. The same first-line, first-to-market and first-in-class strategy applies to the Company's complementary Phase 3 candidate AR-301, which is being developed for the acute treatment of ventilator associated pneumonia (VAP) patients. While AR-320 is expected to be beneficial as a preventative for patients colonized by *S. aureus* bacteria who have not progressed to VAP, AR-301 is intended to treat patients diagnosed with VAP caused by *S. aureus*. With these complimentary product candidates, the Company believes it is well-positioned to be a global leader in the prevention and treatment of VAP caused by *S. aureus*. Enrollment of the Company's AR-301 Phase 3 clinical trial is underway with top-line data expected in mid-2022.
- Announced on August 2nd that it had closed a definitive agreement with a healthcare-focused institutional investor for the purchase and sale of 4,947,556 shares of the Company's common stock (or common stock equivalents) and warrants to purchase up to an aggregate of 2,473,778 shares of the Company's common stock, at an effective at-the-market purchase price of $5.053 per share, in a registered direct offering priced at a premium to the market under Nasdaq rules. The gross proceeds to the Company from this offering were approximately $25.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company. Net proceeds from this offering are expected to fund clinical development, working capital and general corporate purposes well into 2022.
- Achieved the first of four development-based milestones related to the Phase 2a clinical trial of AR-501 from the Cystic Fibrosis Foundation. We received this $1.0 million payment in October 2021.

"The third quarter was defined by the successful acquisition of the Phase 3-ready asset suvratoxumab (AR-320) and the addition of two new shareholders, AstraZeneca and a key institutional investor," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "Our expanding product pipeline is expected to produce multiple near-term clinical milestones, including the AR-301 Phase 3 top-line data in mid-2022, the AR-501 Phase 2a data in and the first-in-human clinical study of AR-712, both in 1H2022. Together with our strengthened financial position from our August 2021 offering, I believe we are in a great position to build our leadership in the respiratory health space."

**Clinical Program Update**

***AR-301:*** AR-301 is being evaluated in a Phase 3 clinical study as an adjunctive treatment to standard of care antibiotics in *S. aureus* VAP patients. The ongoing AR-301 Phase 3 study remains blinded, and the independent Data Monitoring Committee with access to unblinded data continues to monitor study subjects for safety and has not conveyed any safety concerns (i.e., thus far an un-remarkable safety profile). The Company is seeing improved patient enrollment, which had previously been impacted by the pandemic due to the prioritization of the intensive care units (ICU) around the world to COVID-19 patients, and it anticipates enrollment will be completed in the first half of 2022.

The trial represents the first ever Phase 3 superiority clinical study evaluating immunotherapy with a fully human mAb to treat acute pneumonia in the ICU setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

**AR-320 (suvratoxumab)**: The Company announced the licensing of this Phase 3-ready asset from AstraZeneca in July 2021. A multinational, randomized, double blinded, placebo-controlled Phase 2 study (n=196 patients) showed that mechanically ventilated ICU patients colonized with *S. aureus* who are treated with suvratoxumab, a fully human mAb, saw a relative risk reduction of pneumonia by 32% in the overall ITT study population, and by 47% in the under 65-year-old population, which is the target population in the planned Phase 3 study. The relative risk reduction in the target population reached statistical significance and was also associated with a substantial reduction in the duration of care needed in the ICU and hospital. The Company is in discussions with the European Medicines Agency (EMA) and FDA and expects to launch its Phase 3 study of AR-320 in early 2022.

***AR-501:*** The Company initiated its Phase 2a study to evaluate the safety, pharmacokinetic, and preliminary efficacy evaluation in cystic fibrosis (CF) patients in the first quarter of 2021. The Phase 2a is actively enrolling patients with a goal of 42 cystic fibrosis adult patients at full enrollment. The Company expects to report top-line data from this study during the first half of 2022.

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 Phase 1/2a clinical trial is a randomized, double-blinded, placebo-controlled single ascending dose and multiple ascending dose 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 Phase 1/2a clinical trial can be viewed on www.clinicaltrials.gov using identifier NCT03669614.

***AR-712:*** AR-712 is a cocktail of two mAbs, AR-711 and AR-720, designed to lower the barrier to treatment coverage of non-hospitalized SARS-CoV-2 (i.e., COVID-19) patients by using a convenient, self-administered inhaled dosage presentation. The two mAbs that comprise AR-712 were discovered from convalescent COVID-19 patients and target the receptor-binding domain (RBD) region of the spike protein of the original SARS-CoV-2 virus. AR-712 binds and neutralizes the SARS-CoV-2 Delta variant virus at a highly effective level (~20ng/mL) and binding viral neutralization analyses project that AR-712 will be effective against all variants on the U.S. Centers for Disease Control's Variants of Interest and Variants of Concern lists. AR-711 is confirmed by the CoVIC consortium (NIAID, Bill and Melinda Gates Foundation, Wellcome Trust, MasterCard Impact Fund and others) to be among the top five most potent mAbs out of over 350 COVID-19 mAbs that entered the CoVIC evaluation program. In a mouse model of SARS-CoV-2 infection, the AR-711 mAb effectively protected infected animals at the lowest parenteral dose tested (0.5 mg/kg).

The AR-712 mAbs are engineered to be long-acting in blood for up to six to twelve months. A proprietary formulation enables AR-712 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-712 are expected to commence in 1H2022.

***AR-701***: During the quarter, Aridis continued to characterize this cocktail of fully human mAbs discovered from its in-house ΛPEX mAb discovery platform that is directed at multiple envelope proteins of the SARS-CoV-2 virus.

**Fiscal 2021 Third Quarter Results:**

- **Cash**: Total cash and cash equivalents as of September 30, 2021, were approximately $18.2 million.
- **Revenues:** *Grant Revenue* increased to $0.4 million for the three months ended September 30, 2021, from zero for the three months ended September 30, 2020, due to achievement of the first of four Phase 2a clinical trial milestones related to the evaluating AR-501 for the treatment of Cystic Fibrosis under the award from the CF Foundation in the three months ended September 30, 2021.
  - *License revenue* increased to approximately $0.1 million for the three months ended September 30, 2021 from zero for the three months ended September 30, 2020 due to the recognition of revenue related to the out-licensing and product discovery agreement with Kermode Biotechnologies, Inc., which was entered into in February 2021.
- **Research and Development Expenses:** Research and development expenses increased by approximately $15.7 million from approximately $4.2 million for the three months ended September 30, 2020, to approximately $19.8 million for the three months ended September 30, 2021. The components of this increase are:
  - a one-time expense of approximately $11.5 million related to the AR-320 license agreement that we entered into with Medimmune Ltd. during Q3'21, of which approximately $6.5 million of the Company's common stock was issued to Medimmune Ltd. and a $5.0 million cash payment that is due to Medimmune Ltd. by the end of 2021;
  - an increase of approximately $3.0 million in spending on clinical supplies manufacturing activities to prepare for our upcoming AR-320 Phase 3 trial;
  - an increase of approximately $0.8 million in spending on research and development activities for our COVID-19 programs; and
  - an increase of approximately $0.4 million in spending on clinical trial activities and drug manufacturing expenses for the Phase 2a study of our AR-501 program.
- **General and Administrative Expenses:** General and administrative expenses increased by approximately $68,000 from approximately $1.6 million for the three months ended September 30, 2020 to approximately $1.7 million for the three months ended September 30, 2021 which was due primarily to increases in Delaware franchise taxes, professional service fees, patent related expenses, and other general facility related costs, partially offset by a decrease in personnel related costs.
- **Interest Income, net:** Interest income, net decreased by approximately $5,000 from approximately $6,000 for the three months ended September 30, 2020, to approximately less than $1,000 for the three months ended September 30, 2021, due primarily to lower average cash balances during the three months ended September 30, 2021 as compared to the same period in 2020.
- **Other Income:** Other income increased by approximately $23,000 from zero for the three months ended September 30, 2020, to approximately $23,000 for the three months ended September 30, 2021, which relates to income from a sublease agreement we entered into with a tenant in March 2021 to sublet a small portion of our Los Gatos facility. There was no sublease agreement or related income during the three months ended September 30, 2020.
- **Net Loss:** The net loss available to common stockholders for the three months ended September 30, 2021, was approximately $21.0 million, or $1.94 net loss per share, compared to a net loss available to common stockholders of approximately $5.8 million, or $0.65 net loss per share, for the three months ended September 30, 2020. The weighted average common shares outstanding used in computing net loss per share available to common stockholders was 12,454,119 and 8,923,374 for the three months ended September 30 of 2021 and 2020, 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). 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-320** (*S. aureus*). AR-320 is a fully human mAb for prevention of pneumonia with statistically significant Phase 2 data in the target population of those ≤ 65 years of age, recently published in Lancet Infectious Diseases journal. A Phase 3 study of AR-320, licensed from AstraZeneca, is expected to begin in the fourth quarter of 2021.

**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 2a clinical study in healthy volunteers and CF patients.

**AR-712** (COVID-19). AR-712 is a cocktail of two fully human IgG1 mAbs, AR-711 and AR-720, that are directed against the receptor binding domain of the SARS-CoV-2 virus. AR-712 is being developed to treat non-hospitalized mild to moderate COVID-19 patients by inhalation using a nebulizer.

**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-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 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.

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, 2020 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.**
**Consolidated Balance Sheets**
**(in thousands)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| | *(unaudited)* | |
| Cash and cash equivalents | $ 18,221 | $ 8,232 |
| Other current and noncurrent assets | 7,864 | 6,885 |
| Total Assets | $ 26,085 | $ 15,117 |
| Total Liabilities | $ 30,240 | $ 23,798 |
| Total stockholders' deficit | (4,155) | (8,681) |
| Total liabilities and stockholders' deficit | $ 26,085 | $ 15,117 |

**Aridis Pharmaceuticals, Inc.**
**Consolidated Statements of Operation**
**(in thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | *(unaudited)* | | *(unaudited)* | |
| Revenue | $ 515 | $ — | $ 548 | $ 1,000 |
| Operating Expenses* | | | | |
| Research and development | 19,842 | 4,161 | 29,370 | 12,725 |
| General and administrative | 1,699 | 1,631 | 5,337 | 4,853 |
| Total operating expenses | 21,541 | 5,792 | 34,707 | 17,578 |
| Loss from operations | (21,026) | (5,792) | (34,159) | (16,578) |
| Other income (expense) | | | | |
| Interest income, net | 1 | 6 | 2 | 77 |
| Other income | 23 | — | 52 | — |
| Gain on extinguishment of Payroll Protection Program loan | — | — | 722 | — |
| Share of loss from equity method investment | — | — | — | (9) |
| Net loss | $ (21,002) | $ (5,786) | $ (33,383) | $ (16,510) |

| | | | | |
|---|---|---|---|---|
| Deemed dividends | (3,141) | — | (4,127) | — |
| Net loss available to common stockholders | $ (24,143) | $ (5,786) | $ (37,510) | $ (16,510) |
| Weighted-average common shares outstanding used in computing net loss per share available to common stockholders, basic and diluted | 12,454,119 | 8,923,374 | 11,314,058 | 8,922,052 |
| Net loss per share available to common stockholders, basic and diluted | $ (1.94) | $ (0.65) | $ (3.32) | $ (1.85) |
| *Includes stock based-compensation as follows | | | | |
| Research and development | $ 170 | $ 156 | $ 502 | $ 431 |
| General and administrative | 410 | 406 | 1,198 | 1,131 |
| | $ 580 | $ 562 | $ 1,700 | $ 1,562 |

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