Aridis Pharmaceuticals

Aridis Pharmaceuticals Announces Second Quarter 2019 Results

SAN JOSE, Calif., Aug. 12, 2019 /PRNewswire/ -- **Aridis Pharmaceuticals, Inc.** (Nasdaq: ARDS), a biopharmaceutical company focused on the discovery and development of targeted immunotherapies using fully human monoclonal antibodies (mAbs) to treat life-threatening bacterial infections, today reported financial and corporate results for the second quarter ended June 30, 2019.

Second Quarter Highlights and Recent Developments

- Remained on schedule to report top line data in Q3 2019 for AR-105's global Phase 2 clinical trial for the treatment of ventilator-associated pneumonia (VAP) caused by *Pseudomonas aeruginosa (P. aeruginosa)*.
- Received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) and The European Medicines Agency (EMA) for AR-501, an inhalable therapy being clinically tested for the treatment of chronic lung infections in cystic fibrosis patients.
- Received Qualified Infectious Diseases Product (QIDP) and Fast-Track designations from the FDA for AR-501.
- Maintained enrollment pace of AR-501's Phase 1/2a clinical trial with top-line data from healthy subjects expected towards the end of Q1 2020 and from cystic fibrosis patients in Q2 2021.
- Advanced Phase 3 global clinical trial of AR-301 targeting gram-positive *Staphylococcus aureus* (*S. aureus)* in critically ill VAP patients. Remained on track to report interim data in Q1 2020 with top line data expected in late 2020.
- Bolstered leadership team with appointment of Dr. Susan Windham-Bannister to Board of Directors.
- Announced the execution of a $10 million equity purchase transaction at a premium of approximately 31% and entered into an option agreement with Serum International B.V. ("SIBV"), an affiliate of the Serum Institute of India Private Limited ("SIIL"), for exclusive rights to license products and mAb discovery platform technology MabIgX®.
- Received an upfront cash payment of $5 million upon execution of the option agreement with SIBV and will receive an additional $10 million upon execution of the license agreement by August 31, 2019.

"The second quarter proved to be a significant period of growth for the company," commented Vu Truong, Ph.D., Chief Executive Officer of Aridis Pharmaceuticals. "In addition to maintaining the development pace of our clinical programs, I am very pleased with the work performed by the entire team as we evaluated and ultimately brought on SIBV as a shareholder and potentially a commercial partner for certain ex-U.S. and ex-EU markets. SBIV's parent company, SIIL, is a bona fide leader in vaccines and biologics that has in recent years acquired formidable capabilities in monoclonal antibody development and manufacturing. I am particularly pleased that the option agreement not only includes a selection of our products, but also provides SIBV access to our ground-breaking MabIgX® platform for new asset identification and development, which is a testament to the quality of the technology."

Clinical Program Update

AR-105*:* The Company is pleased to report that AR-105's global Phase 2 clinical trial is on track to report topline data in Q3 2019. The trial, which was fully enrolled during the first quarter of 2019, consists of 158 treated patients and is evaluating AR-105, a broadly active, fully human IgG1 monoclonal antibody for the treatment of VAP caused by gram-negative *P. aeruginosa.* Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03027609.

AR-105 has the potential to treat all patient populations infected by *P. aeruginosa* and is not limited to any subset of *P. aeruginosa* infected patients. Therefore, pending the outcome of the Phase 2 trial, Aridis will evaluate whether there is a need to embark on a separate Phase 2/3 clinical trial for AR-101, another pipeline product which is a highly specific monoclonal antibody targeting *P. aeruginosa* lipopolysaccharide serotype O11 that accounts for a subset of approximately 22% of all *P. aeruginosa* hospital-acquired infections worldwide.

AR-301*:* During the second quarter, Aridis continued enrolling its Phase 3 global clinical trial for AR-301, which targets gram-positive *S. aureus* in critically ill VAP patients. The trial, which was initiated in the first quarter of 2019, is expected to enroll 240 patients at approximately 140 clinical centers in 20 countries. Interim data is expected in Q1 2020 and top line data is expected in late 2020. Participating centers in all countries are following 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 (ICU) setting. Details of the study can be viewed on www.clinicaltrials.gov using identifier NCT03816956.

AR-301 is a broadly active, 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 second quarter, Aridis continued enrolling patients in its Phase 1/2a clinical trial of this inhalable formulation of gallium citrate being evaluated to treat 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 in Q1 2020 and the Phase 2a segment with cystic fibrosis subjects in Q2 2021.

AR-501, which is being developed in collaboration with the Cystic Fibrosis Foundation, has been granted by the FDA both Fast Track and QIDP designations. In addition, during the second quarter, the FDA and recently (July 19, 2019), the EMA granted AR-501 Orphan Drug Designation.

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 and Recent Developments

During the second quarter, the Company enhanced its leadership team with the appointment of Susan Windham-Bannister, Ph.D., to its Board of Directors. Dr. Windham-Bannister, an internationally recognized expert in advising biopharma companies on market access, growth optimization and portfolio management strategies, currently serves as President and CEO of Biomedical Growth Strategies., LLC and Managing Partner of Biomedical Innovation Advisors, LLC, an advisory firm serving the healthcare industry which she founded with Dr. Harvey Lodish, co-founder of Genzyme. As Aridis prepares for multiple data readouts over the course of 2019 and into the first quarter of next year, Dr. Windham-Bannister's expertise will be utilized in addressing key areas such as healthcare policy, drug reimbursement and commercial strategy for the Company's product candidates.

On July 30, 2019, Aridis announced that the Company entered into equity purchase and option agreements with SIBV, the world's largest vaccine manufacturer by dose. SIBV invested $10 million into Aridis and received 801,820 shares of the Company's restricted common stock at a price of approximately $12.47 per share, which represented a premium of approximately 31% to the closing share price of Aridis common stock on July 29, 2019.

Pursuant to the option agreement, Aridis received a $5 million upfront payment and will receive an additional $10 million upon execution of the license agreement by August 31, 2019. The upfront payment is refundable should the parties not complete the license agreement. Furthermore, assuming the license agreement is executed, Aridis expects to receive as much as $42.5 million in future milestone payments for achieving product development and commercial objectives, along with royalties on net sales.

The license agreement will provide SIBV with the right to in-license Aridis' clinical stage programs AR-301(VAP), AR-105 (VAP) and AR-101 (hospital acquired pneumonia (HAP)). These license rights will be exclusive and to a limited territory which includes markets outside of the U.S., Europe, Canada, UK, China, Australia, New Zealand and Japan. Also, the agreement will include the option to acquire an exclusive, worldwide license (excluding China) to AR-201, a preclinical fully human mAb for the prevention of respiratory syncytial virus (RSV). In addition, SIBV may elect to collaborate with Aridis to utilize MabIgX® to identify and advance up to five SIBV wholly-owned programs. MabIgX® is Aridis' proprietary technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs.

Fiscal 2019 Second Quarter Results:

- **Cash**: Total cash and cash equivalents as of June 30, 2019 was $8.5 million. In July 2019, we received net proceeds of approximately $9.2 million from the sale of 801,820 shares of restricted common stock. In addition, the Company received an upfront cash payment of $5 million upon the execution of an option agreement. This upfront payment is refundable should the parties not complete the license agreement by August 31, 2019.
- **Revenues:** Total revenues for the quarter ended June 30, 2019 was zero, a decrease of $22,000 over the same period in 2018.
- **Research and Development Expenses:** Research and development expenses for the quarter ended June 30, 2019 were $6.7 million, an increase of $2.8 million over the same period in 2018 due primarily to

an increase in spending on clinical trial activities and drug manufacturing for our AR-301 program and an increase in spending on drug manufacturing for our AR-105 Phase 3 program, partially offset by a decrease in spending on clinical trial activities for our AR-105 Phase 2 program, and a decrease in spending on toxicology studies related to our AR-501 program.

- **General and Administrative Expenses:** General and administrative expenses for the quarter ended June 30, 2019 were $1.6 million, an increase of $0.9 million over the same period in 2018 due primarily to an increase in professional service fees, an increase in personnel related expenses, an increase in directors' and officers' liabilities insurance expense, and an increase in Delaware franchise taxes and patent related fees.
- **Interest and Other Income, net:** Interest and other income, net for the quarter ended June 30, 2019 was $69,000, an increase of approximately $1,000 over the same period in 2018. These increases were due primarily to a higher rate of return on our cash balance partially offset by a lower average cash balance.
- **Change in Fair Value of Warrant Liability:** As a result of all warrants to purchase preferred stock being converted into warrants to purchase common stock upon our IPO in August 2018, there was no warrant liability recorded at the end of the second quarter of 2019. There was a $3.1 million gain attributed to a decrease in the fair value of the warrant liability in the second quarter of 2018.
- **Net Loss:** The net loss available to common shareholders for the quarter ended June 30, 2019 was $8.4 million, or ($1.03) per share, compared to a net loss available to common shareholders of $2.0 million, or ($11.78) per share, for the quarter ended June 30, 2018. It should be noted that there were 166,373 common shares outstanding during the second quarter of 2018 and until the completion of the Company's IPO in August 2018. Moreover, there were convertible preferred shares outstanding until the time of the IPO which earned dividends that were distributed as additional shares of preferred stock. All preferred shares were converted to common stock upon the completion of the IPO on August 16, 2018. There were 8.1 million common shares outstanding after the completion of the IPO when all preferred shares were converted to common shares. At December 31, 2018 and at June 30, 2019, there were 8.1 million shares common shares outstanding.

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 MabIgX® technology platform to rapidly identify rare, potent antibody-producing B-cells from patients who have successfully overcome an infection to produce mAbs. 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 and high mAb productivity. MabIgX® also allows for the selection of any antibody isotype depending on the optimal effector function required for treating the target infection. By bypassing the humanization and binding sequence optimization steps, and the entire process of generation of genetically engineered antibody producing cell lines, MabIgX® enables high gross-margins and expedited progression to clinical development.

The Company has generated multiple clinical stage mAbs targeting bacteria that that cause life-threatening infections such as VAP and 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-105 (VAP). AR-105 is a fully human IgG1 mAb targeting gram-negative *P. aeruginosa* alginate in VAP patients. AR-105 is currently being evaluated in a global Phase 2 clinical study.

AR-101 (HAP). AR-101 is a fully human immunoglobulin M, or IgM, mAb targeting *P. aeruginosa* liposaccharides serotype O11, which accounts for approximately 22% of all *P. aeruginosa* hospital acquired pneumonia cases worldwide. A plan for the next clinical study will be communicated following the availability of Phase 2 clinical data for AR-105.

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 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 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, 2018 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)

	June 30, 2019	December 31, 2018
	(unaudited)	
Cash and cash equivalents	$ 8,519	$ 24,237
Other current and noncurrent assets	7,355	7,374
Total Assets	$ 15,874	$ 31,611
Total Liabilities	$ 5,012	$ 5,297
Total stockholders' equity	10,862	26,314
Total liabilities and stockholders' equity	$ 15,874	$ 31,611

Aridis Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operation

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018

		(unaudited)		(unaudited)
Revenue	$ —	$ 22	$ 1,022	$ 344
Operating Expenses*				
Research and development	6,653	3,885	13,771	10,511
General and administrative	1,613	687	3,254	1,753
Total operating expenses	8,266	4,572	17,025	12,264
Loss from operations	(8,266)	(4,550)	(16,003)	(11,920)
Other income (expense)				
Interest and other income, net	69	68	185	142
Change in fair value of warrant liability	—	3,058	—	3,021
Equity in net loss from equity method investment	(186)	—	(628)	—
Net loss	$ (8,383)	$ (1,424)	$ (16,446)	$ (8,757)
Preferred dividends	$ -	$ (535)	$ -	$ (1,352)
Net loss available to common stockholders	$ (8,383)	$ (1,959)	$ (16,446)	$ (10,109)
Weighted-average common shares outstanding, basic and diluted	8,107,290	166,373	8,106,484	166,373
Net loss per common share, basic and diluted	$ (1.03)	$ (8.56)	$ (2.03)	$ (52.63)
Preferred dividends, basic and diluted	$ —	$ (3.22)	$ —	$ (8.13)
Net loss per share available to common stockholders, basic and diluted	$ (1.03)	$ (11.78)	$ (2.03)	$ (60.76)
*Includes stock based-compensation as follows				
Research and development	$ 198	$ 139	$ 371	$ 280
General and administrative	305	179	549	509
	$ 503	$ 318	$ 920	$ 789

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