

Aridis Pharmaceuticals (ARDS - \$12.12)

Initiating Coverage – A Differentiated Platform to Fulfill Unmet Medical and Financial Needs

We are initiating coverage of Ardis Pharmaceuticals (ARDS) with a Buy rating and \$23 price target. ARDS uses its differentiated MabIgX antibody discovery platform for targeted immunotherapy using fully human mAbs as add-on therapy to antibiotics for hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP). With high-throughput screening of B-cells and direct manufacturing of mAbs, ARDS can reduce antibody discovery and development by up to one year. AR-301 represents their lead product candidate and targets gram (+) *S. aureus*. The Phase 2a results reached the primary endpoints (no SAEs and expected PK), and showed encouraging trends of efficacy (improvements in time of ventilator, microbiological eradication rate and overall ICU stays). ARDS intends to begin their first pivotal Phase 3 trial in 2H18 with interim readout expected in 2H19. The second value driver consists of AR-105, which was also granted Fast Track Designation (FTD) and targets gram (-) *P.aeruginosa*. Following the successful Phase 1 trial (no SAEs and expected PK), ARDS initiated a global Phase 2 trial in 2Q17 and expects data in 2H19. AR-101 represents their third value driver and targets gram (-) *P. aeruginosa* serotype O11, which was granted Orphan Drug Designation (ODD) in both the US and EU. A successful Phase 1 showed numeric improvement in initial clinical resolution rate, time on ventilator or in ICU and all-cause mortality. ARDS now plans to initiate a Phase 2/3 pivotal trial in 2H19. With a fairly late stage differentiated clinical pipeline that could more efficiently fulfill unmet medical and financial needs, we are initiating coverage with a Buy rating and \$23 PT.

- **Strong Phase 2a data de-risks larger upcoming Phase 3s.** With no SAEs, in-line PK profile, as well as efficacy data trending favorably with a small n number; we see their first Phase 3 (n=210) as relatively de-risked.
- **Platform's flexibility, gram (-) targets in late stage development.** As gram (-) bacteria tend to be more resistant to antibiotics, we are encouraged by the outreach of the MabIgX platform with ARDS's AR-105 and AR-101.
- **Pharmacoeconomic benefit of MabIgX hard to overstate.** With mechanically ventilated patients costing 3X to treat and requiring 2X the ICU stay, we believe ARDS's platform could add significant financial value.
- **Initiate with a Buy rating, \$23 PT.** Our PT is based on a sum-of-the-parts analysis with AR-301 at \$13/share, AR-105 at \$5/share, AR-101 sales at \$2/share and \$3/share for cash and tech.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY19E	(1.85)	(1.81)	(1.23)	(1.18)	(5.81)	NA
FY18E	(1.40)A	(1.45)	(1.34)	(1.76)	(5.99)	NA
FY17A	--	--	--	--	(5.38)	NA
FY16A	--	--	--	--	--	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	ARDS
Rating:	Buy
Price Target:	\$23

Trading Data:

Last Price (09/07/2018)	\$12.12
52-Week High (08/14/2018)	\$13.85
52-Week Low (09/07/2018)	\$11.25
Market Cap. (MM)	\$95.6
Shares Out. (MM)	7.9

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5 Key Reasons to own Aridis Pharmaceuticals

- 1. Strong Phase 2a data de-risks larger upcoming Phase 3 studies.** With no SAEs, in-line PK profile, as well as efficacy data trending favorably with a small n number; we see their first Phase 3 (n=210) as relatively de-risked. Their Phase 2 trial was able to demonstrate statistically significant reduction in ventilation days with adjunctive AR-301 treatment (pooled) vs. placebo + SOC (p<0.01). Additionally, AR-301 showed consistent trends of higher and faster rate of microbiological cure. As the n number of patients is expected to grow from n=48 (ITT n=25) to n=210 in their first Phase 3, we believe the consistency between these efficacy measurements could help de-risk their upcoming clinical readouts.
- 2. Differentiated platform's flexibility, Gram (-) P.aeruginosa targets in late stage development.** As gram (-) bacteria tend to be more resistant to antibiotics, we are particularly encouraged by the outreach of the MabIgX platform with AR-105 and AR-101. AR-105 attacks HAP/VAP caused by gram (-) P. aeruginosa, which represents an addressable market of ~478,000 patients/year (~30% of the gram (-) market). With no SAEs observed at any dose in their Phase 1 study, we anticipate Phase 2 data readout in 2H19.
- 3. Platform's potential in smaller patient population and future growth.** We see as positive ARDS's ability to use their proprietary technology for different bacterial targets. In fact, their third value driver consists of AR-101 for acute pneumonia caused by P. aeruginosa serotype O11, which consists of only ~20% of the P.aeruginosa HAP/VAP population. AR-101 also showed strong efficacy trends vs. antibiotics alone in all-cause mortality, time to resolution of pneumonia, as well as time on ventilator. With ODD in US and EU, ARDS intends to initiate their pivotal Phase 2/3 in 2H19.
- 4. Pharmacoeconomic benefit of MabIgX hard to overstate.** With daily ICU costs for ventilator pneumonia patients coming in >\$10,000 and >\$30B/year in US healthcare costs from prolonged mechanical ventilation; it is hard to overstate the potential financial benefits of the different ARDS programs.
- 5. Important late stage catalysts around the corner throughout pipeline.** We anticipate AR-301 initiation of their first Phase 3 in 2H18, its interim data readout in 2H19, AR-105 Phase 2 data readout in 2H19 and AR-101 initiation of its pivotal Phase 2/3 in 2H19. We look forward to exciting catalysts in the near future at ARDS.

Figure 1: Upcoming Potential Catalysts

Event	Expected Timing
AR-301 Initiation of 1st phase 3	2H18
AR-301 Interim data readout	2H19
AR-105 phase 2 data readout	2H19
AR-101 initiation of pivotal phase 2/3	2H19

Source: Company Reports; Laidlaw and Company estimates

Valuation

We value ARDS at \$23/share based on a sum-of-the-parts valuation. AR-301 US sales is valued at \$13/share based on a 3.5x multiple of 2027 sales of \$404M, discounted back 9 years at a 32.5% discount rate. AR-105 US sales is valued at \$5/share based on a 3.5x multiple of 2027 sales of \$243M, discounted back 9 years at a 37.5% discount rate. AR-101 US sales is valued at \$2/share based on 3.5x multiple of 2028 sales of \$116M, discounted back 10 years at a 35% discount rate. We value net cash (end 2018) and technology at \$3/share.

Figure 2: Sum-of-the-Parts Analysis

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
AR-301 US sales	\$112,403	\$13.00
AR-105 US sales	\$48,322	\$5.00
AR-101 US sales	\$20,266	\$2.00
Cash (end '18) & tech value	\$24,988	\$3.00
	\$185,713	\$23.00
2018 fully diluted shares out (000)		8,832

Source: Company Reports; Laidlaw and Company estimates

Company Description

Aridis Pharmaceuticals (ARDS) is a late-stage biopharmaceutical company focused on the discovery and development of targeted immunotherapy using fully human monoclonal antibodies (mAbs), to treat life-threatening infections. mAbs represent a fundamentally new treatment approach in the infectious disease market and are designed to overcome key issues associated with current therapies, including drug resistance, short duration of response, negative impact on the human microbiome, and lack of differentiation in treatment options. Their proprietary product pipeline primarily targets hospital-acquired pneumonia (HAP), and ventilator-associated pneumonia (VAP). Three of their product candidates have exhibited promising preclinical and clinical data available from two completed studies and are in pivotal trial stage. Their lead product candidate, AR-301 (Salvecin), targets the alpha toxin produced by gram (+) bacteria *Staphylococcus aureus* (*S. aureus*), a common pathogen associated with HAP and VAP. ARDS has conducted an end-of-Phase 2 meeting with the FDA, and expects to initiate a Phase 3 trial for AR-301 in 2H18. Additionally, they are developing AR-105 (Aerucin), and AR-101 (Aerumab). AR-105 targets gram (-) bacteria *Pseudomonas aeruginosa* (*P. aeruginosa*) and has been granted Fast-Track Designation (FTD) by the FDA. They initiated a global Phase 2 trial for AR-105 in HAP and VAP patients in 2Q17 and expect data in 2H19. AR-101 also targets gram (-) bacteria *P. aeruginosa* and has been granted orphan drug designation (ODD) in the US and EU. They plan to initiate a Phase 2/3 pivotal trial for AR-101 in the 2H19.

Platform Technology and Market

The majority of candidates from their product pipeline are derived by employing their differentiated antibody discovery platform called MabIgX, which is designed to comprehensively screen B-cells and isolate human antibody-producing B-cells from individuals who have either successfully overcome an infection by a particular pathogen or have been vaccinated against a particular pathogen. Ultimately ARDS sees these B-cells as potentially protective for other patients. MabIgX also allows for rapid, high-throughput screening of B-cells and direct manufacturing of mAbs. As a result, they can significantly reduce time for antibody discovery and manufacturing compared to conventional approaches by up to one year. They intend to continue to use their MabIgX platform to generate new product candidates for bacterial, viral and other infectious diseases.

Figure 3: Competitive Advantages of MabIgX Platform

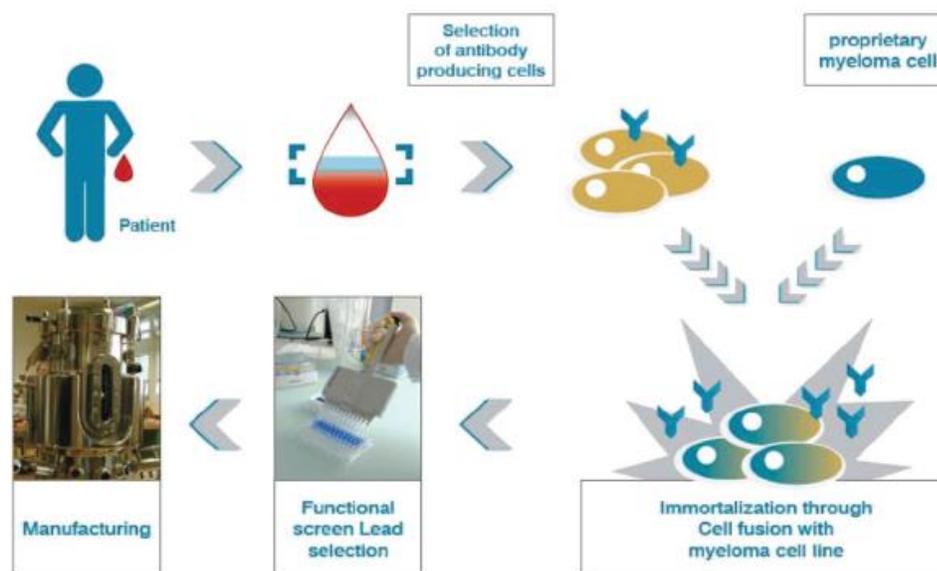
MabIgX Technology Advantages
Rapidly screen for rare and potent B-cells to produce differentiated mAb product candidate and expeditiously progress product candidates from target identification to clinical development.
Broad applicability to produce immunologically and clinically relevant product candidates across all relevant immunoglobulin isotypes (IgG, IgA, IgM, IgE antibodies).
Discovery of mAb product candidates with high efficacy due to recognition of epitopes relevant to humans
Generation of mAb product candidates well tolerated with potential for multiple administrations due to low immunogenicity
Ability to rapidly progress to clinical manufacturing by avoiding the need for recombinant antibody engineering processes and production cell lines.

Source: Company reports

The first step in their process is the selection of immunized or convalescent patients, for which they have collaborations. Then they apply hybridoma technology, whereby the human B-cells of the donors are isolated, transiently immortalized and fused to the proprietary heteromyeloma cell line to form stable hybridoma lines. This allows them to overcome a major challenge in developing human therapeutic mAbs, which is the inability to easily select and culture antigen-induced mAb-producing human B-cells and to use them to construct continuous mAb-producing cell lines. It is important to isolate antibodies of the proper isotype based on the infection targeted and the desired reaction of the human immune system. Their MabIgX technology enables the isolation of the isotype of an antibody that the human immune system utilizes to combat a

particular pathogen and isolate all different isotypes. All those antibodies retain their effector function, which is an important factor in the regulation of an effective immune reaction in the human body.

Figure 4: MablgX B-cell Discovery and Manufacturing Technology



Source: Company S1 report

The initial clinical indication for these compounds is adjunctive therapeutic treatment with standard of care (SOC), antibiotics for HAP and VAP. Mortality and morbidity in the intensive care units (ICU), remain a real concern. Current SOC antibiotics used to treat HAP and VAP typically involve a combination of several broad spectrum antibiotics that are prescribed empirically at the start of treatment. The specific empirical antibiotic regimens that are prescribed vary widely among physicians, and generally resulted in modest clinical benefits for

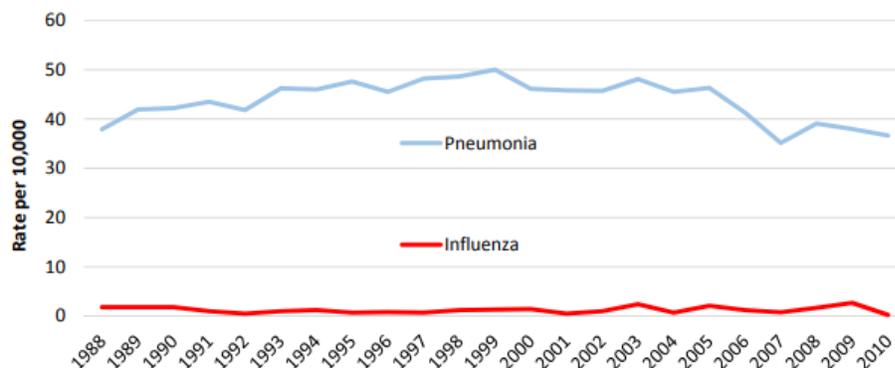
a number of reasons, including the frequent mismatch of the antibiotics regimen to the etiologic agent and/or infection by an antibiotic resistant strain.

Recently, rapid diagnostic tests have been introduced that allow the identification of infection-causing agents within hours. These increasingly common tests allow physicians to prescribe a targeted anti-infective drug, rather than a broad-spectrum antibiotic. We find this development particularly interesting as it doesn't compete directly with antibiotics due to differentiation in MOA.

There are ~3M cases of pneumonia reported in the US/year and ~628,000 annual cases of HAP and VAP caused by Gram (-) bacteria and MRSA (DRG, 2016). Additionally, these patients are typically at high risk of mortality, which is compounded by other life-threatening co-morbidities and the rise in antibiotic resistance. Epidemiology studies estimate that the probability of death attributed to *S. aureus* ranges from 29%-55% and *P. aeruginosa* ranges from 24%-76%.

In 2010, there were > 1M hospitalizations due to pneumonia. In 2014, the hospitalization rate of pneumonia was 36.6/10,000, which represents the second lowest since 1988.

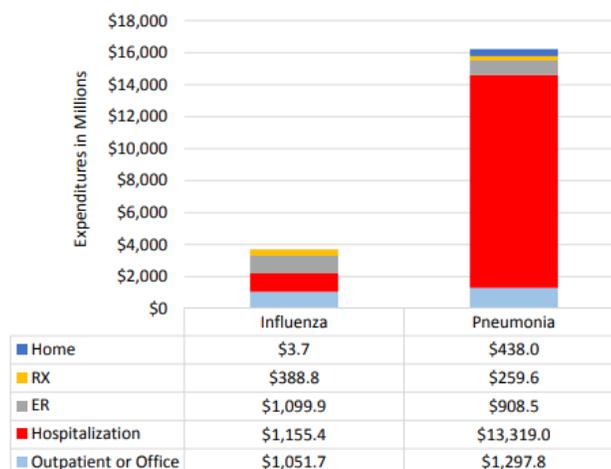
Figure 5: Pneumonia and Influenza hospitalization rate through the years



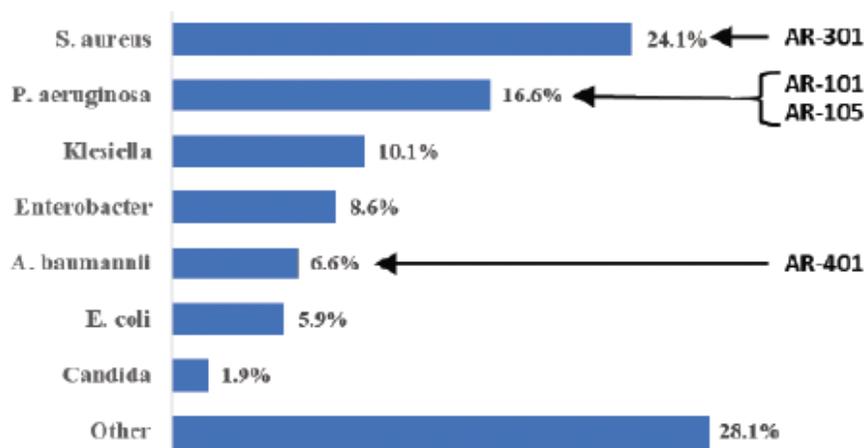
Source: CDC, 1988-2010

Additionally, pneumonia infections can prolong patient stays in ICUs and the use of mechanical ventilation, creating a major economic burden. For example, ICU cost of care for a ventilated pneumonia patient is ~\$10,000/day, and the duration of ICU stay is typically 2X that of a non-ventilated patient (Infection Control and Hospital Epidemiology, 2010). The average cost of care per pneumonia patient is ~\$41,250 which increases 86% for HAP/VAP patients to ~\$76,730. ARDS estimates that their three clinical mAb candidates have an addressable market of \$25B and the potential to address ~325,000 HAP and VAP patients in the US. In 2013, ~\$16.2B went to pneumonia related healthcare expenses in the US.

Figure 6: Pneumonia and Influenza Healthcare Expenditures by Disease and Type of Service



Source: AHRQ, MEPS, 2013

Figure 7: Most Common Bacterial Pathogens in ICU Pneumonia

Source: Company S1 report

The lack of antibiotic product differentiation is traced to the usage of non-inferiority clinical trial designs that is common practice for most of the antibiotics that have been marketed to date and we are particularly encouraged that ARDS opted for superiority.

AR-301 – IgG1 mAb for HAP/VAP S. Aureus

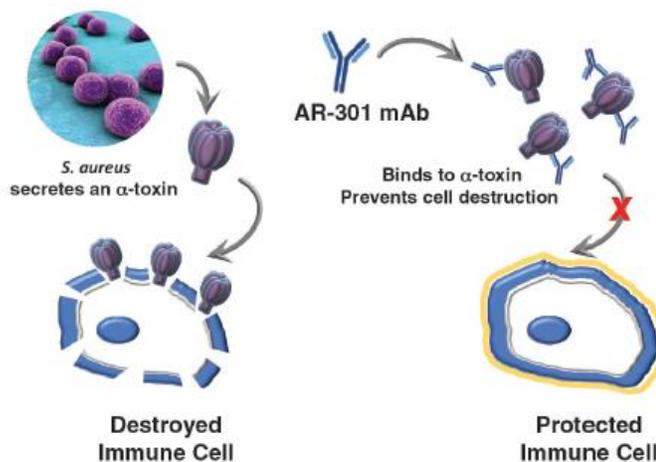
AR-301 (Salvecin, or tosatouxumab) is a fully human immunoglobulin 1 (IgG1), mAb targeting the gram (+) bacteria *S. aureus* alpha toxin. The company is developing AR-301 initially as an adjunctive immunotherapy in combination with SOC antibiotics to treat acute pneumonia caused by *S. aureus* infection. ARDS filed an IND for AR-301 on 6/5/15. They have recently completed a Phase 2a trial in HAP and VAP patients. The trial met its primary endpoint of tolerability as AR-301 was generally well tolerated with no SAEs, related to the product candidate, and its PK properties were consistent with that of human IgG1. In addition, the trial showed consistent trends towards benefit in various patient benefits related endpoints, including improvements in time on ventilator, microbiological eradication rate, and overall ICU stays for AR-301 + SOC antibiotics vs. antibiotics alone. They expect to initiate a Phase 3 trial in VAP

patients in the 2H18. As mentioned previously, AR-301 has been granted FTD and ODD in the EU.

With ~790,000 hospitalizations involving mechanical ventilation in 2005, the national costs were ~\$27B (Crit Care Med, 2010). Infections due to MRSA represent a high-value segment of the overall antibiotics market. The WW market for existing therapies for MRSA infections was >\$800M in 2015. The progressively aging population is expected to increase the number of MRSA infections that result in HAP. Moreover, MRSA infections are associated with significantly longer hospital stays, repeated hospitalizations and increased healthcare costs. Currently, the median hospital stay of a patient with VAP is 29 days, and the average length of ICU stay is 19 days. The median total hospitalization costs for a VAP patient is ~\$198,000. Current SOC antibiotics for MRSA pneumonia is dominated by five antibiotics: Linezolid, Daptomycin, Vancomycin, Ceftaroline, and Tigecycline; which combined have ~90% market share. There is a significant need for new anti-MRSA agents given the *S. aureus* resistance rate of 31%-53%.

AR-301 binds to alpha-toxin with high affinity and prevents its assembly into an active complex, which prevents alpha-toxin-mediated breakdown of cell membranes, or lysis, of erythrocytes, human lung cells and immune cells such as lymphocytes. This prevention of killing of host cells, may protect the patient from further progression of pneumonia and systemic infections. During infection and active proliferation, *S. aureus* is metabolically more virulent, geared toward higher toxin production than during its more sessile colonization stage. In contrast to other programs targeting *S. aureus* colonization, AR-301 targets the active, disease causing infection stage. There is no commercially available product that specifically neutralizes the pathogenic effects brought about by *S. aureus* toxins. Additional indications for AR-301 may include any *S. aureus* infection, particularly surgical site infections, blood stream infections, endocarditis, and skin and soft tissue infections such as diabetic ulcers and non-healing wounds.

Figure 8: AR-301's MOA



Source: Company S1 Report

ARDS recently completed a Phase 2a clinical trial with AR-301 plus SOC antibiotics compared to SOC antibiotics alone to treat HAP and VAP caused by *S. aureus*.

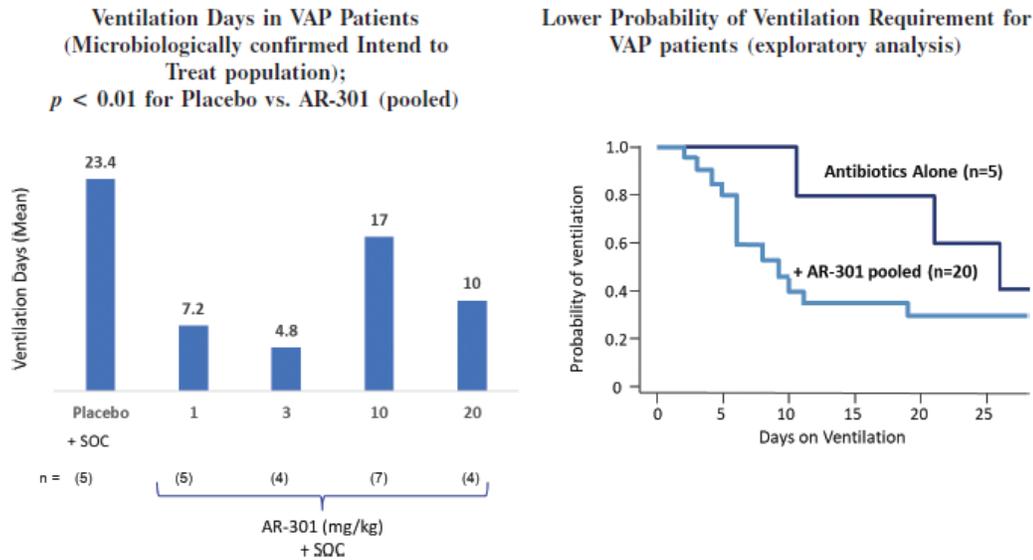
Figure 9: Clinical Trial Design

Phase 2a: Safety, Tolerability, PK/PD of AR-301 + SOC	
Aim	Evaluate safety, tolerability, PK, efficacy and PD of single IV administration of AR-301 + SOC in patients with severe pneumonia caused by <i>S. aureus</i>
Design	randomized, double-blinded, placebo-controlled, active comparator, ascending dose
Dosing	1) n=6 with 1mg/kg AR-301 + SOC; 2) n=8 with 3mg/kg AR-301 + SOC; 3) n=10 with 10mg/kg AR-301 + SOC; 4) n=8 with 20mg/kg AR-301 + SOC and 4) n=16 with placebo + SOC. 31 sites across Belgium, France, Spain, UK and US
Endpoints	1) Incidence of adverse events. 2) Multiple endpoints of clinical improvements including time to extubation.
Patients	n=48
Safety	well tolerated. Few (2.8%) AE and no SAEs related to AR-301. 36 AE observed: septic shock (n=3), anaemia (n=3), bacteraemia (n=2), sepsis (n=2), acute respiratory failure (n=2), hypoxia (n=2), pancreatic abscess (n=1), pneumonia (n=1), CO2 increase (n=1), gamma-glutamyltransferase increase (n=1), platelet count increase (n=1), abnormal prothrombin level (n=1), duodenal ulcer (n=1), epistaxis (n=1), hypoventilation (n=1), pleurisy (n=1), pulmonary embolism (n=1), haemodynamic instability (n=1), hypotension (n=1), shock haemorrhagic (n=1), superior vena cava syndrome (n=1), vena cava thrombosis (n=1), cardiac arrest (n=1), coronary artery stenosis (n=1), ventricular tachycardia (n=1), multi-organ failure (n=1), pyrexia (n=1), hepatic failure (n=1), hepatocellular injury (n=1), hypoalbuminaemia (n=1), malnutrition (n=1), heparin-induced thrombocytopenia (n=1), coma (n=1) peripheral motor neuropathy (n=1), renal tubular necrosis (n=1), post procedural haemorrhage (n=1) and subdural haematoma (n=1). 6 deaths but none related to AR-301.
Results	Drug was generally well tolerated and showed comparable safety to placebo. Exploratory analysis of the VAP subgroup of n=25, numeric clinical improvement of antibody treated patients vs placebo in time to extubation. Also, patients treated with AR-301 showed trends toward higher rate of microbiological eradication and reduction in number of hospital or ICU days. PK profile of AR-301 consistent with human IgM, with plasma half-life of 23 to 31 days and supports single-dose administration for the pneumonia indication. When subset of 25 patients with VAP was assessed, Kaplan-Meier showed separation of the group of patients with AR-301 + SOC vs placebo + SOC. In exploratory analysis with all 4 treated cohorts pooled and compared vs placebo, stat sig was achieved p<0.01. Additionally, eradication (cured pneumonia) was seen in 25 (78.1%) patients treated with AR-301 + SOC and 10 (62.5%) of placebo + SOC. Time to eradication trended shorter in treatment arm.

Source: Company Reports

Over the first 28 days of the study, the length of stay in the ICU and in the hospital both showed a modest decrease in the AR-301 plus SOC groups as compared to placebo plus SOC-treated subjects, however, this difference did not reach stat sig. Time ventilated in the pooled AR-301 treated cohorts (n=20) showed an exploratory p<0.01 reduction in the subset of patients with VAP as compared to the placebo plus SOC cohort (n=5).

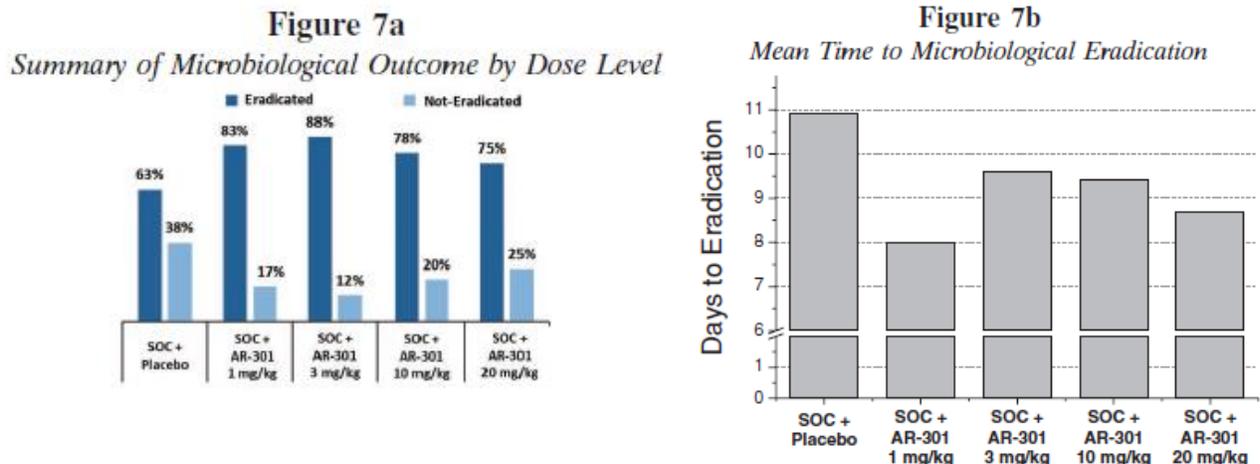
Figure 10: Impact Adjunctive AR-301 Treatment on Mechanical Ventilation Time (VAP subgroup)



Source: Company S1 Report

Although SOC antibiotics were effective, the results suggest that the addition of AR-301 to SOC treatment may increase the rate of microbiological eradication, and may reduce time to eradication.

Figure 11: Microbiological dose levels and Mean Time to Microbiological Eradication – Consistently trending favorably



Source: Company Reports

The company plans to conduct two pivotal clinical trials in pneumonia patients for regulatory approval in the US and EU. Following discussions with clinical experts in the field, >15% improvement of AR-301 plus SOC over placebo plus SOC on these efficacy outcomes is deemed to be clinically meaningful. Assuming a treatment effect of clinical cure of 85% versus 65% in active drug treated

patients would provide 90% power to demonstrate a statistically significant result. They also reached agreement with the FDA on the size of the safety database required for approval and plan to include the following safety endpoints: immunogenicity, adverse events, and standard safety laboratory tests. They expect to enroll the first subject in the 2H18, plan to include an interim data readout in the 2H19, and complete enrollment by the 1H20.

Figure 12: Clinical Trial Design

Phase 3 #1	
Aim	Evaluate efficacy of single IV administration of AR-301 + SOC in patients with severe pneumonia caused by <i>S. aureus</i>
Design	randomized, double-blind, placebo-controlled active comparator AR-301 (20mg/kg) + SOC vs placebo + SOC. 130 clinical sites in over 15 countries
Dosing	AR-301 (20mg/kg) + SOC vs placebo + SOC
Endpoints	1) clinical cure
Patients	n=210
Safety	
Results	interim readout in 2H19

Source: Company Reports

AR-105 – IgG1 mAb for Acute Pneumonia from *P. Aeruginosa*

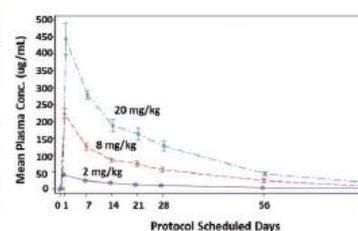
AR-105 (Aerucin) is a fully human IgG1 mAb targeting the gram (-) bacteria *P. aeruginosa* that ARDS is currently developing as an adjunctive immunotherapy to treat acute pneumonia. They filed an IND for AR-105 on 1/8/15 and in a recent Phase 1 trial, AR-105 was well-tolerated at all dose levels with no SAEs, and its PK profile was consistent with that of human IgG1. In preclinical studies, AR-105 exhibited broad binding profile and mediated killing of >90% of clinical isolates tested. AR-105 also demonstrated protective effects in prophylaxis animal models and synergistic effect in combination with antibiotics. They initiated a global Phase 2 trial in HAP/VAP patients in the 2Q17 and expect to report data in 2H19. As previously mentioned, AR-105 has been granted FTD by the FDA.

Figure 13: AR-105 Phase 1

A) Safety summary — No SAEs observed at any dose levels

	AR-105 2.0 mg/kg (n = 5)	AR-105 8.0 mg/kg (n = 6)	AR-105 20 mg/kg (N = 5)
AEs	15	15	16
Related AEs	0	2	4
Infusion site edema	0	1	0
Blood pressure diastolic decr.	0	0	2
Back pain	0	0	1
Headache	0	0	1
Somnolence	0	1	0

B) Pharmacokinetic profile was typical of a non-tissue binding IgG1, with a plasma $T_{1/2}$ life ~21 days



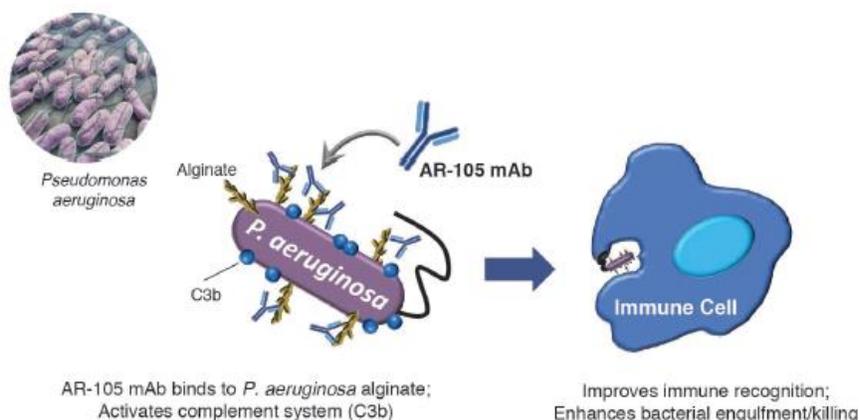
Source: Company S1 Report

Pseudomonas infection is caused by strains of bacteria found widely in the environment and represents one of the most common gram (-) bacteria associated with a number of human infections. Drugs targeting gram (-) bacteria must cross both the inner and outer membranes of the bacterial cell, as compared to those directed against gram (+) bacteria, which must only cross one cell membrane. As a result, gram (-) bacteria tend to be more resistant to antibiotics and the body's own immune system. Multidrug-resistant *Pseudomonas* can be deadly for patients in critical care. According to the Centers for Disease Control and Prevention (CDC), ~51,000 healthcare-associated *P. aeruginosa* infections occur in the US/year. More than 6,000 (13%), of these are multidrug-resistant, leading to ~400 deaths/year. Cephalosporin and beta lactamases are the most commonly prescribed first line therapy to treat *P. aeruginosa* pneumonia, but these drugs have a resistance rate of ~30%.

As is the case with HAP caused by *S. aureus*, there is substantial mortality associated with HAP caused by *P. aeruginosa* and an annual worldwide incidence of ~450,000 patients (Gram Negative Infections, 2009). The healthcare-associated gram (-) infections worldwide cost is projected to be >\$3.6B in 2026 (Pharmapoint, 2018). Additionally, the markets for lung and blood-borne infection such as sepsis are characterized by patients who either have a disruption of the normal protective barrier to infection or have an underlying chronic disease such as cystic fibrosis, non-cystic fibrosis bronchiectasis, and chronic obstructive pulmonary disease (COPD). These leave the lungs and systemic organs in a weakened state and susceptible to infections by *P. aeruginosa*. It is estimated that the addressable patient population in the US, EU, and Japan combined is ~478,000 patients.

AR-105 specifically binds to *P. aeruginosa* alginate expressed on the cell surface of *P. aeruginosa*. AR-105 binding activates the C3b component of the complement system, a part of the immune system which binds to the bacterial cell wall in a process called antibody opsonization. The cell surface bound antibody and C3b are then recognized by receptors on the cell surface of immune cells called polymorphonuclear leukocytes, which results in the phagocytosis, or ingestion, and killing of the bacterial cell.

Figure 14: AR-105 MOA



Source: Company S1 Reports

ARDS recently completed an open-label, single ascending dose Phase 1 clinical trial of AR-105 in which all subjects received one intravenous dose of AR-105. AR-105 was shown to be well tolerated in the recently completed Phase 1 clinical trial in healthy volunteers. They are currently in a global Phase 2 clinical study with this product candidate and project data readout in the 1H19.

Figure 15: Clinical Trial Design

Phase 2	
Aim	Evaluate efficacy of AR-105 + SOC vs SOC in patients with VAP caused by Gram (-) <i>P. aeruginosa</i>
Design	randomized, double-blind, active comparator trial with a single-dose of AR-105 (20mg/kg) + SOC or placebo + SOC. At ~ 90 sites in about 15 countries in US, EU and Asia
Dosing	placebo: antibiotics a line (up to 55 patients). Antibiotics + 20mg/kg (up to 55 patients)
Endpoints	1) clinical cure rate. 2) Time to removal of ventilator, microbiological cure, all-cause mortality, time to clinical resolution, days in ICU, hospitalization days, antibiotics utilization
Patients	n=110 patients with VAP caused by Gram (-) <i>P. aeruginosa</i>
Safety	
Results	Initiated 2Q17, data 2H19

Source: Company reports

AR-101 – IgM mAb for *P. Aeruginosa* serotype O11

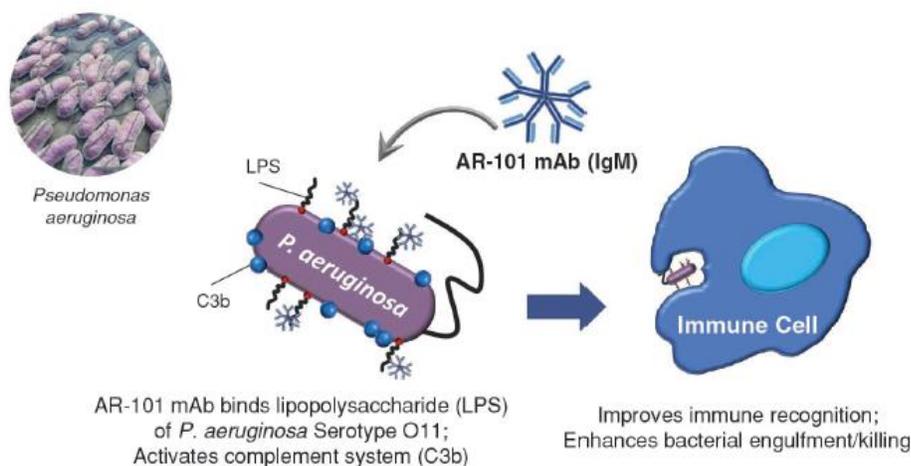
AR-101 (Aerumab) is a fully human immunoglobulin M (IgM) mAb targeting the gram (-) bacteria *P. aeruginosa* serotype O11. ARDS filed an Investigational Medicinal Product Dossier (IMPD), with the EU on 10/22/04. They plan to file an IND after the initiation of their Phase 2/3 pivotal trial described below. They have completed a Phase 1 trial in healthy adults and a Phase 2a trial in HAP and VAP patients. In the Phase 2a trial, AR-101+ SOC antibiotics was generally well tolerated. The per protocol population demonstrated numeric improvement over

standalone antibiotics across multiple clinical endpoints, including initial clinical resolution rate, time on ventilator or in ICU, and all-cause mortality, was seen. They plan to initiate a Phase 2/3 pivotal trial in the 2H19. As mentioned previously, AR-101 has been granted ODD in the US and EU.

AR-101, which they are initially developing as an adjunct therapy for the treatment of HAP and VAP caused by *P. aeruginosa* serotype O11, binds to the lipopolysaccharide (LPS) on the cell surface of *P. aeruginosa*. Serotype O11 is one of the most prevalent *P. aeruginosa* serotypes in HAP and VAP, representing ~23% of cases (Crit Care, 2014). It is estimated that the addressable patient population in the US, EU and Japan combined is ~95,600 patients. ARDS intends to incorporate a companion diagnostic test based on polymerase chain reaction (PCR) technology that can rapidly identify *P. aeruginosa* serotype O11 strains in order to identify those patients most likely to respond to AR-101.

Upon binding, AR-101 mediates the deposition of the human complement to the surface of *P. aeruginosa* bacteria. This antibody-complement complex leads to improved recognition by the host immune cells, which results in engulfment and killing of the bacteria. AR-101, like IgM antibodies in general, provides several advantages towards more effective bacterial killing. They possess 10 binding sites rather than 2 for IgG, and they are 100X-1,000X more effective than IgG at binding and/or activating key enzymes that facilitate the killing of *P. aeruginosa*. As a result, IgM antibodies are becoming more prevalent as candidates for drug therapies.

Figure 16: AR-101 MOA



Source: Company S1 report

The company has completed a Phase 1 safety and tolerability trial of single ascending doses of AR-101 in healthy adults and an open-label Phase 2a safety and PK trial of up to 3 single doses of AR-101 in pneumonia patients. These studies suggested AR-101 to be generally well tolerated in both healthy adults and HAP and VAP patients.

Figure 17: Clinical Trial Design

Phase 1	
Aim	Evaluate Safety and Tolerability AR-101 in pneumonia patients
Design	randomized, double-blind, placebo-controlled
Dosing	0.1, 0.4, 1.2 and 4 mg/kg and placebo
Endpoints	Safety and PK
Patients	n=32
Safety	no SAEs and no subject discontinued due to an AE. Mild to moderate AE and all resolved without sequelae, and the incidence of AE did not increase with the dose. No activation of an immune response against AR-101
Results	PK characteristics were consistent with the characteristics of a human IgM, with a serum half-life between 70 and 95 hours

Source: Company reports

Comparison of the per protocol population (n=13) of the Phase 2a study, which excluded 4 patients from the ITT population (n=17) because they did not complete the treatment regimen, and a contemporaneous control cohort suggested that AR-101 therapy may improve survival, cure rate of the index pneumonia, and time to cure pneumonia.

Figure 18: Clinical Trial Design

Phase 2	
Aim	Evaluate Safety and PK of AR-101 in patients with pneumonia
Design	open-label phase 2a
Dosing	3 IV infusions of 1.2mg/kg of AR-101 given over 2 hours on days 1, 4 and 7 for a total dose of 3.6mg/kg
Endpoints	Safety and efficacy
Patients	n=18
Safety	14 SAE were experienced by 6 patients: GI bleeding (n=3), cardiac and respiratory arrest (n=2), multi organ failure (n=2), hyperbilirubinemia and cholestasis (n=1), neutropenia (n=1), low count of platelets (n=1), activated partial thromboplastin time (n=1), prolongation (n=1), septic shock (n=1), cholestasis (n=1) and troponin increase (due to cardiac arrest) (n=1). An event of cardiorespiratory arrest was judged as related to AR-101 and events of hyperbilirubinemia and cholestasis, although pre-existent, were deemed possibly related. In both cases, investigators assessed that a contribution by AR-101 to the adverse event couldn't be excluded with certainty.
Results	30-day survival rates were 82% and 100% in the ITT:n=17 and the per protocol (n=13). Clinical resolution of pneumonia was observed in 76% of patients in ITT and 100% in the per protocol population. Microbiological resolution was observed in 6 patients (35% of ITT and 31% of per protocol population). Time to resolution was 14 days in ITT and 9 days in per protocol. Time to extubation was 22 days in ITT and 13 days in the per protocol populations.

Source: Company reports

In parallel, they also conducted a contemporaneous cohort study of the incidence and outcome of HAP and VAP caused by various *P. aeruginosa* serotypes in critically ill patients. The data were extracted from the medical files of the patients selected according to eligibility criteria similar to those of their Phase 2a study. Cohort patients infected with *P. aeruginosa* serotype O11 (n=14) had a lower survival rate, cure rate, and microbiological resolution rate, as well as longer mean times on ventilator and in the ICU as compared to patients in their Phase 2a clinical trial who received a complete treatment of three 1.2 mg/kg doses of AR-101.

Figure 19: AR-101 Phase 2 Trial Comparison of Adjunctive (AR-101 + Antibiotics) to Cohort (Antibiotics Alone) Groups

	AR-101 + Antibiotics Intent-to-Treat (n=17)	AR-101 + Antibiotics Per Protocol (n=13)	Contemporaneous Cohort Study Serotype O11 (n=14)
Mortality (%)	18% (3/17 pts)	0% (0/13 pts)	21% (3/14 pts)
Time to Initial Clinical Resolution of Pneumonia (mean)	14 days ± 10 days SD	9 days ± 2.9 days SD	19 days ± 10 days SD
Initial Clinical Resolution of Pneumonia (%)	76% (13/17 pts)	100% (13/13 pts)	64% (9/14 pts)
Clinical Resolution of Pneumonia on Day 30	65% (11/17 pts)	85% (11/13 pts)	57% (8/14 pts)
Microbiological Resolution on Day 30	35% (6/17 pts)	31% (4/13 pts)	14% (2/14 pts)
Time on Ventilator or Time in ICU*	22 days	13 days	21 days

* Kaplan-Meier time-to-event estimation of the times where 50% of patients had experienced the event.
'pts' = patients

Source: Company S1 reports

ARDS plans to initiate a double-blind, randomized, placebo-controlled Phase 2/3 clinical trial as an adjunct to SOC antibiotics 2H19. The clinical trial will enroll adult patients with HAP or VAP. As with the prior Phase 2a study, the primary efficacy endpoint in this study will include clinical cure rate. Time to clinical cure was an endpoint that achieved statistical significance in the Phase 2a study ($p=0.005$) and will be evaluated in detail in the Phase 2/3 study. They will also assess microbiological endpoints as well as select pharmacoeconomic endpoints as well as PK.

Rest of Pipeline

AR-401 – mAb for infections from *Acinetobacter baumannii*

AR-401 is their mAb discovery program aimed at treating infections caused by *A. baumannii*, which is a gram (-) pathogen that is rapidly emerging as a serious threat to patients in hospital care. Its high level of resistance to first-line antibiotic therapies, potential to survive prolonged periods on dry surfaces and ability to form biofilms rapidly on artificial devices, such as catheters and ventilators, have made it particularly virulent. The clinical impact of *A. baumannii* infections can have serious adverse consequences with crude mortality rates reaching 30% in infected ICU patients. Moreover, infection with *A. baumannii* leads to an increased length of stay at the ICU of an average of 15 extra days. Their planned next step for this program is to select a lead therapeutic mAb and advance into in vitro potency testing and in vivo assessment of therapeutic efficacy in an *A. baumannii* challenge mouse model.

AR-201 – IgG1 mAb for RSV

AR-201 is a fully human IgG1 mAb with high affinity for respiratory syncytial virus (RSV), glycoprotein F and neutralizes diverse clinical isolates of RSV. In in vivo preclinical studies, AR-201 has shown to be 12X more potent than Synagis in a head-to-head comparison study, a currently marketed drug for pediatric RSV. AR-201 has also been shown to bind to RSV strains that are resistant to Synagis.

RSV is the leading cause of lower respiratory tract illness in infants and young children WW. In premature neonates, RSV infection results in high levels of morbidity. In the US alone, there are > 234,000 hospitalizations and 14,000 deaths per year attributable to RSV. The only prophylaxis for RSV is Synagis (palivizumab), a humanized murine mAb that targets the RSV glycoprotein F and has been shown to reduce the rate of RSV-associated hospitalization by ~50%. Synagis-resistant RSV strains are rising, which emphasize the need for additional anti-RSV products against different epitopes.

AR-501 – broad spectrum anti-infective for CF

AR-501 (Panaecin) is a broad-spectrum small molecule anti-infective the company is developing in addition to their targeted mAb product candidates. This product candidate is currently in late preclinical studies. AR-501 is administered as an inhalable aerosol to treat lung infections in CF patients. Preclinical studies have shown that mice infected with *P. aeruginosa* can be rescued with a single inhalation exposure of aerosolized AR-501. They expect to file the IND, application and initiate a Phase 1/2a trial in healthy adults and CF patients in the 2H18. They are developing AR-501 as an anti-infective therapy to manage both chronic lung infections in CF patients and acute pneumonia in HAP and VAP patients. AR-501 exhibits broad antimicrobial activity against antibiotic resistant gram (-) and gram (+) bacteria in free-living, or planktonic, and biofilm communities, as well as against fungi. They believe AR-501's unique combination of broad spectrum antimicrobial activity against pathogens, lower propensity to develop resistance than inhaled TOBI (tobramycin) and Cayston (aztreonam), and less frequent dosing as compared to SOC, make it an ideal candidate for treatment of chronic polymicrobial infections, such as lung infections in CF patients.

Competition

ARDS is initially developing mAbs as an adjunct therapy to be used with SOC antibiotics, which is a unique approach to treating lung infections that does not directly compete with antibiotics. Additionally, in contrast to antibiotics, the dosing frequency of mAbs is 1X or 2X/month and may require only a single administration. Several companies are developing mAbs to treat infections, including Merck (MRK), Medimmune, Arsanis (ASNS), and Alopexx. ASNS recently announced that their Phase 2 clinical trial was stopped following interim analysis showing futility. As the ASNS trial was different in indication, study design, and patient population, we do not believe that the outcome of this trial adds risk to AR-301's Phase 3 clinical trial.

Figure 20: Comparison with ASNS' ASN100 – Important Differences in Trials

Company	ARDS	ASNS
Product	AR-301	ASN100
Target	Aphatoxin	6 Toxins
S. aureus metabolic state	Rapidly proliferation	Sessile biofilm-colonized
Clinical Trial Design	Treatment	Prevention
Patient Population	Severe, S.a. infected	Asymptomatic, S.a. colonized but not infected
Desired effect size	20%	50%
# treated/patient benefit	1 to 1	≥6 to 1

Source: Company Reports

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

Management

Vu Truong, Ph.D. Founder, CEO and Director. Dr. Truong is a founder of Aridis and was elected CEO in 2014 after having served as the company's CSO since 2005. He has > 20 years of experience in biopharmaceutical drug development, having held positions of increasing responsibilities in companies which were eventually acquired by larger entities, including Gene Medicine (sold to Megabios), Aviron (sold to MedImmune) and MedImmune (sold to Astra Zeneca). Having maintained a life-long interest in infectious diseases, he has focused on researching and developing innovative human monoclonal antibodies and vaccines designed to address life-threatening infections. His product development experience includes FluMis, Synagis mAb and a number of other monoclonal antibody-based therapeutics. Dr. Truong is the principal architect of Aridis' technologies, which includes a range of anti-infective products and pharmaceutical processing technologies. He received his Ph.D. in Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine.

Wolfgang Dummer, M.D., Ph.D., CMO. Dr. Dummer has > 20 years of clinical trial and drug development experience, most recently as VP of Clinical Development at BioMarin Pharmaceutical (BMRN), where he led the clinical development and approval of Vimizim (elosulfase alpha), now BMRN's leading marketed compound. For 11 years prior, he held various senior roles in Clinical Research and Development at Genentech. He also spent 3 years studying at the Scripps Research Institute in La Jolla, California. Dr. Dummer has authored and co-authored > 50 peer-reviewed journal articles, and is a board-certified clinical dermatologist and allergist/immunologist. He earned his M.D. degree and his Ph.D. in Medical Sciences from the Technical University of Munich Medical School.

Fred Kurland, J.D., MBA, CFO. Fred Kurland has > 35 years of experience in corporate finance, most recently as the CFO of Xoma. He has a long and distinguished career as CFO of a number of biotechnology companies including Bayhill Therapeutics, Corcept Therapeutics, Genitope Corporation, Aviron, Protein Design Labs and Applied Immune Sciences. Previously, he held a number of financial management positions at Syntex Corporation between 1981 and 1995 including VP and Controller between 1991 and 1995. He received his B.S. from Lehigh University and his J.D. and M.B.A. degrees from the University of Chicago.

Figure 22: Quarterly Income Statement

Aridis Pharmaceuticals						
Quarterly income statement						
(\$000 except per share)	2017A	2018E				2018E
	Year	1QA	2QE	3QE	4QE	Year
Revenues						
contract revenue						
collaboration revenue	771					
grant revenue	89	322	500	750	1000	2,572
Total Revenue	\$860	\$322	\$500	\$750	\$1,000	\$2,572
Expenses:						
COGS (% of US Revenue)	0	-	-	-	-	-
Gross Margin	860	322	500	750	1,000	2,572
G&A	3,160	1,066	1,000	1,250	1,500	4,816
R&D	17,438	6,626	7,000	9,000	12,500	35,126
Total operating expenses	20,598	7,692	8,000	10,250	14,000	39,942
Loss from operations	(19,738)	(7,370)	(7,500)	(9,500)	(13,000)	(37,370)
Interest and other income (expense), net	234	74	75	75	75	299
change in fair value of warrant liability	(5,152)	(38)				(38)
Net loss	(24,656)	(7,334)	(7,425)	(9,425)	(12,925)	(37,109)
Preferred dividends	(2,793)	(817)	(1,000)	(1,000)	(1,000)	(3,817)
NI/(loss) as reported	(27,449)	(8,151)	(8,425)	(10,425)	(13,925)	(40,926)
Earning per Share (EPS)	(\$5.38)	(\$1.40)				
Adj EPS ex-1x & non-cash	(\$5.38)	(\$1.40)	(\$1.45)	(\$1.34)	(\$1.76)	(\$5.99)
Weighted avg. shares (000)	5,103	5,807	5,807	7,807	7,907	6,832
Fully diluted shares (000)	5,103	5,807	5,807	9,807	9,907	8,832

Source: Company Reports; Laidlaw & Company estimates

Figure 23: Annual Income Statement

Aridis Pharmaceuticals					
Annual income statement					
(\$'000's except per share)	2016A	2017E	2018E	2019E	2020E
Revenues					
contract revenue	\$2,068				
collaboration revenue	\$201	\$771			
grant revenue		\$89	\$2,572	\$2,300	\$2,300
Total sales	\$2,269	\$860	\$2,572	\$2,300	\$2,300
COGS	1,927	0	0	0	0
Gross margin	342	860	2,572	2,300	2,300
R&D	6,261	17,438	35,126	51,000	58,000
SG&A	1,965	3,160	4,816	7,500	11,000
Adj. Net Income	(8,887)	(27,449)	(40,926)	(59,800)	(70,300)
NI/(loss) as reported	(8,887)	(27,449)	(40,926)	(59,800)	(70,300)
Adj-EPS ex-non-cash		(\$5.38)	(\$5.99)	(\$5.81)	(\$4.61)
EPS as reported		(\$5.38)			
Shares out (000)		5,103	6,832	10,294	15,257
Fully diluted shares (000)		5,103	8,832	12,294	17,257

Source: Company Reports; Laidlaw & Company estimates

Figure 24: Balance Sheet Statement

Aridis Pharmaceuticals					
Balance sheet					
(\$000's except per share)	<u>2017</u>	<u>1Q18A</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>
ASSETS:					
Current assets					
Cash and cash equivalents	\$25,096	\$20,387	\$9,988	\$17,213	\$42,013
Accounts receivable					
Prepaid Expenses and others	244	634			
Other current assets					
Total current assets	25,340	21,021	9,988	17,213	42,013
PP&E	750	1,182	1,500	1,750	2,000
Intangible assets, net	43	42			
other assets	345	345			
Total Assets	26,478	22,590	11,488	18,963	44,013
LIABILITIES					
Current liabilities:					
accounts payable	933	3,499	1,000	1,250	1,500
accrued liabilities	2,121	1,783	2,500	2,750	3,000
deferred revenue	120	797	1,000	1,250	1,500
Total current liabilities	3,174	6,896	4,500	5,250	6,000
warrant liability	11,868	11,906	12,000	13,000	14,000
Total liabilities	15,042	18,802	16,500	18,250	20,000
Shareholder's equity					
series A convertible preferred stock	74,202	74,202	75,000	80,000	85,000
common stock					
additional paid-in capital	(15,140)	(14,637)	8,540	69,065	157,665
accumulated deficit	(47,626)	(55,777)	(88,552)	(148,352)	(218,652)
Total shareholders' equity	11,436	3,788	(5,012)	713	24,013
Total liabilities & net worth	26,478	22,590	11,488	18,963	44,013

Source: Company Reports; Laidlaw & Company estimates

Figure 25: Cash Flow Statement

Aridis Pharmaceuticals Statement of cash flows					
(\$'000's except per share)					
	<u>2017A</u>	<u>1Q18A</u>	<u>2018E</u>	<u>2019E</u>	<u>2020E</u>
Operating Cash Flow					
Net Loss	(24,656)	(7,334)	(40,926)	(59,800)	(70,300)
Depreciation and amortization	62	51	50	75	100
stock-based compensation expense	1,608	503	2,000	2,250	2,500
amortization of debt discount and debt issuance costs					
change in fair value of preferred stock warrants	5,152	38			
changes in assets and liabilities			458	500	500
accounts receivable	67				
prepaid expenses and other current assets	(37)	(296)			
other assets	(304)				
Cash from operations	(17,557)	(4,437)	(38,418)	(56,975)	(67,200)
Investing Activities					
purchase of property and equipment	(698)	(272)			
Cash from investing	(698)	(272)	(1,000)	(1,250)	(1,500)
Financing Activities					
Proceeds from issuance of preferred stock, net of is	21,060				
Proceeds from issuance of common stock			24,310	65,450	93,500
Repayment of line of credit					
Cash from financing	21,060		24,310	65,450	93,500
Change in cash	2,805	(4,709)	(15,108)	7,225	24,800
Cash, start of period	22,291	25,096	25,096	9,988	17,213
Cash, end of period	25,096	20,387	9,988	17,213	42,013

Source: Company Reports; Laidlaw & Company estimates

DISCLOSURES:

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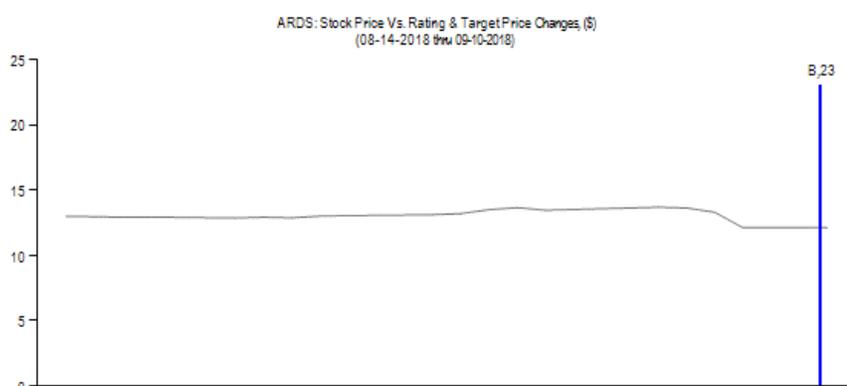
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Additional information available upon request.

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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
09/10/2018	Buy (B)	12.12*

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
09/10/2018	23.00	12.12*

* Previous Close 9/7/2018

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	62.50%	21.43%	3.57%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	1.79%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Arsanis (ASNS – Not Rated)

Merck (MRK – Not Rated)

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