



11/14/2019

Outperform

Price: \$5.13

Price Target: \$22.00

Industry

Biotechnology

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Stock Data	
52-Week Range	\$5.05/\$12.62
Avg. Daily Volume	10,478
Market Cap. (MM)	\$45
Shares Out. (MM)	8.7
Float	58.0%
Cash Per Share	\$1.99
Debt-to-Capital	0.0%
Book Value Per Share	\$1.34
Dividend Yield	0.00%
Shares Short	14,586
Insider Ownership	42.0%
Institutional Ownership	0.5%
FY End	Dec
Source: Factset	

EPS Estimates (\$)								
	2018	2019	2020					
1Q	(1.40)A	(0.99)A						
2Q	(0.34)A	(1.04)A						
3Q	(0.51)A	(0.87)A						
4Q	(0.67)A	(0.88)E						
FY	(3.61)A	(3.79)E	(4.05)E					
P/E	NM	NM	NM					
Prev CY		(3.78)E						

Net Income Estimates (\$M)								
	2018	2019	2020					
1Q	(8.2)A	(8.1)A						
2Q	(2.0)A	(8.5)A						
3Q	(7.9)A	(7.6)A						
4Q	(5.4)A	(7.7)E						
FY	(23.5)A	(31.9)E	(46.6)E					
Prev CY		(32.2)E						

Aridis Pharmaceuticals, Inc. (ARDS)

Clinical Programs Advancing w/ Data for AR-301 and AR-501 in Early-2020

Summary

Aridis reported 3Q results that were aligned with expectations. Importantly, the Co. remains on track to report interim data from its AR-301 P3 program in early-2020, and the Phase 1 portion of its P1/2a AR-501 study in 1Q2020.

Key Points

3Q Quick Take: Aridis reported 3Q results that were aligned with expectations, with a net loss of \$7.6MM or EPS of (\$0.87). R&D spending totaled \$6.0MM, supporting ongoing P3 AR-301 and Phase 1/2a AR-501 clinical programs. SG&A totaled \$1.4MM, down from the 2Q level of \$1.6MM.

Proforma Cash Balances at ~\$24MM: Cash balances at quarter end totaled \$17.3MM. Adjusting for \$10MM received in October under its agreement with Serum AMR (SAMR), and cash burn through mid-November, we estimate proforma cash balances at ~\$24MM, which should be sufficient to fund operations for at least 12 months.

Kev Clinical Programs

AR-301 (Salvecin) for Ventilator-Associated Pneumonia: Aridis continues to enroll subjects in its P3 global clinical trial evaluating AR-301 for the treatment of ventilator-associated pneumonia (VAP) attributable to *Staphylococcus aureus* infection. AR-301 is a fully human monoclonal IgG1 antibody that targets *Staphylococcus aureus* alpatoxin as an adjunct therapy for treating critically ill patients with VAP in the ICU setting. The P3 study (NCT03816956) has targeted enrollment of 240 subjects at approximately 125 clinical centers in 20 countries. The P3 study represents the first P3 superiority clinical trial evaluating immunotherapy with a fully human mAb to treat acute pneumonia in the ICU setting. *Interim data from the AR-301 P3 is anticipated in early-2020, with full TLR in early-2021*.

AR-501 for Cystic Fibrosis-Related Lung Infections: AR-501 (inhaled gallium citrate for the treatment of cystic fibrosis-related lung infections) continues enrollment of its Phase 1/2a clinical program (NCT03669614). The Phase 1/2a trial is a randomized, double-blinded, placebo controlled single and multiple dose-ascending study evaluating the safety and pharmacokinetics of inhaled AR-501. The single ascending dose cohorts of healthy volunteers have completed dosing, with the safety monitoring committee recommending proceeding into multiple ascending dose cohorts. Aridis anticipates reporting the Phase 1 portion of the trial in 1Q2020, Results from the Phase 2a multiple-ascending dose study in cystic fibrosis patients with chronic bacterial lung infections is anticipated in the 2Q2021 timeframe.

Valuation Methodology:

We value Aridis' shares using a discount present value method. We calculate the implied enterprise value of AR-301, and AR-101 as the product of forecast US peak sales and a multiple of sales, discounted by forecast years-to-peak with a discount factor adjusted to reflect development risk. Per share value is derived as the quotient of the sum of implied present value of AR-301, and AR-101, respectively, and projected shares outstanding at peak sales. We note that there exists upside to these forecasts as they exclude any contribution from RoW markets and exclude other pipeline candidates at this juncture.

Table 1: Valuation Methodology	
AR-301, US	
US Cases	252,000
Px/Regimen	\$ 10,000
TAM, US	\$ 2,520,000,000
% Penetration, US	35%
Peak Sales, US	\$ 882,000,000
Multiple of Sales	4.0
Enterprise Value	\$ 3,528,000,000
Years-to-Peak, US	7.0
Discount Rate	35.0%
Implied PV, AR-301, US-Only	\$ 431,710,088
AR-101, US	
US Cases	31,000
Px/Regimen	\$ 10,000
TAM, US	\$ 310,000,000
% Penetration, US	20%
Peak Sales, US	\$ 62,000,000
Multiple of Sales	4.0
Enterprise Value	\$ 248,000,000
Years-to-Peak, US	10.0
Discount Rate	50.0%
Implied PV, AR-101, US-Only	\$ 4,300,699
TTL Implied PV of AR-301, 105, 101, US-Only	\$ 436,010,787
Shares Outstanding @ Peak Sales	20,000,000
Implied PV per Share, Excludes Upside Pipeline and fr. RoW	\$ 22.00
Source: Northland Securities, Inc. Estimates	

Risks

An Investment in Aridis Pharmaceuticals, Inc., Involves Risks:

- Clinical and Regulatory Aridis Pharmaceuticals must advance its candidates through clinical trials supporting regulatory submission and approval, with pivotal studies demonstrating clinically meaningful superiority to standard of care (SOC) therapies while being safe and well tolerated. Further, the Company must obtain and sustain marketing authorization in multiple jurisdictions with its products having clinically differentiated labeling. Further, the Company's ability to achieve the target price may be predicated on its ability to develop, discover, in-license and commercialize complementary therapies.
- Commercial and Reimbursement/Payor Any and all of the Company's products must achieve significant market penetration while obtaining reimbursement from entitlement programs, commercial insurance carriers, and other funding sources, in multiple jurisdictions.
- Safety Risk Any safety and/or adverse events associated with any of the Company's products represents a risk to achieving price target.
- Sales, Marketing, and Distribution Any impairment in the Company and/or any of its affiliates to sell, market, or distribute its products in multiple jurisdictions represents a risk to performance.
- **Manufacturing and Supply Chain** Any impairment in the Company or any of its affiliates to procure and produce compliant finished products represents a risk to performance.
- Competition, Generics, and Pricing Aridis' success is predicated on broad commercial acceptance
 of its candidates, and any other products it may develop or in-license, with favorable pricing amid a
 competition from other therapies including generics and biosimilars.
- **Future Capital Needs** Aridis may need to raise additional capital to support development, commercialization of its products, acquisition of complimentary therapies, and to support continuing operations.
- Third Parties Clinical Trials Aridis uses contract research organization (CROs) for a broad spectrum of services including: trial design; patient recruiting and site selection; data analysis; drafting of regulatory submission; and related product development and regulatory-related services. Any failure of third parties ability to fully perform such functions represents a risk.
- Intellectual Property Aridis must be able to enforce the Company's intellectual property. Expenses associated with any arising litigation involving defense of its intellectual property represent a risk to achieving the target.

Aridis Pharmaceuticals, Inc.														
(#'s in 1,000's, except per share data)														
Revenue	<u>1Q19A</u>	2Q19A	3Q19A	<u>4Q19E</u>	FY 2018A	FY 2019E	<u> </u>	Y 2020E	<u>F</u>	Y 2021E	<u> </u>	Y 2022E	1	Y 2023E
Grant Revenue	\$ 1,022	\$ -	\$ -	\$ 1,500	\$ 2,757	\$ 2,522	\$	3,000	\$	1,500	\$	-	\$	-
Collaborative Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$	-	\$	-	\$	-	\$	-
Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$	-	\$	-	\$	2,500	\$	20,000
Total Revenue	\$ 1,022	\$ -	\$ -	\$ 1,500	\$ 2,757	\$ 2,522	\$	3,000	\$	1,500	\$	2,500	\$	20,000
COGS	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$	-	\$	-	\$	750	\$	5,000
R&D Expense	\$ 7,188	\$ 6,653	\$ 6,011	\$ 7,750	\$ 23,000	\$ 27,602	\$	40,000	\$	45,000	\$	47,500	\$	50,000
SG&A Expense	\$ 1,641	\$ 1,613	\$ 1,384	\$ 1,534	\$ 3,874	\$ 6,172	\$	10,000	\$	12,750	\$	17,500	\$	35,000
Total Operating Expenses	\$ 8,829	\$ 8,266	\$ 7,395	\$ 9,284	\$ 26,874	\$ 33,774	\$	50,000	\$	57,750	\$	65,750	\$	90,000
Operating Income (Loss)	\$ (7,807)	\$ (8,266)	\$ (7,395)	\$ (7,784)	\$ (24,117)	\$ (31,252)	\$	(47,000)	\$	(56,250)	\$	(63,250)	\$	(70,000)
Other Income (Expense), net	\$ (326)	\$ (186)	\$ (192)	\$ 75	\$ 655	\$ (629)	\$	450	\$	500	\$	550	\$	650
Earnings (Loss) b4 Tax	\$ (8,133)	\$ (8,452)	\$ (7,587)	\$ (7,709)	\$ (23,462)	\$ (31,881)	\$	(46,550)	\$	(55,750)	\$	(62,700)	\$	(69,350)
Tax Provision	\$ -	\$ -	\$ -	\$ -	\$ -									
Net Income Available to Common	\$ (8,133)	\$ (8,452)	\$ (7,587)	\$ (7,709)	\$ (23,462)	\$ (31,881)	\$	(46,550)	\$	(55,750)	\$	(62,700)	\$	(69,350)
EPS	\$ (0.99)	\$ (1.04)	\$ (0.87)	\$ (0.88)	\$ (3.61)	\$ (3.79)	\$	(4.05)	\$	(4.13)	\$	(3.92)	\$	(3.75)
Shares Outstanding, Weighted-Average Source: Northland Securities, Inc., & Co. Reports	8,106	8,107	8,694	8,769	6,491	8,419		11,500		13,500		16,000		18,500

Company Description

Aridis Pharmaceuticals, Inc. is a late-stage specialty biopharmaceutical company focusing on discovering, developing, and commercializing targeted immunotherapies using fully human monoclonal antibodies (mAbs) to treat life-threatening bacterial infections. Fully humanized monoclonal antibodies represent a major potential breakthrough by engaging the patient's immune response while overcoming the deficiencies of broad spectrum antibiotics including multi-drug resistance (MDR), short duration of response, disruption of the microbiome, and lack of differentiation among standard of care (SOC) treatment options. Aridis' pipeline is comprised of six wholly-owned candidates in various stages of development that target difficult-to-treat, multi-drug resistant (MDR) bacterial pathogens, primarily associated with hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP). Aridis Pharmaceuticals, Inc. is headquartered in San Jose, California, and completed its initial public offering on August 13, 2018.

Analyst Certification

I, Carl Byrnes, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

Important disclosures



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Outperform (BUY) – Outperform the S&P 500 by at least 10%.

Market Perform (HOLD) – Perform within 10% above or below the S&P 500.

Underperform (SELL) – Underperform the S&P 500 by at least 10%.

Rating Distribution Breakdown as of 11/14/2019

			IB S	erv./ Past 12Mos.
Rating Category	Count	Percent	Count	Percent
Buy [OP]	151	75.12%	26	17.22%
Hold [MP]	45	22.39%	2	4.44%
Sell [UP]	5	2.49%	0	0.00%

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Aridis Pharmaceuticals (ARDS)

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