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EQUITY RESEARCH
Company Report

March 8, 2019

Aldeyra Therapeutics (ALDX - $7.64)

Healthcare/Biotechnology

Ticker:	**ALDX**
Rating:	**Buy**
Price Target:	**$30.00**

4Q18: Catalyst-Rich Period to Come with Reproxalap in AC ALLEVIATE Trial Data Readout Leading the Charge

This morning, ALDX reported 4Q18 financial results with a net loss of ($10.6MM) vs. Laidlaw and the Street ($11.2MM) estimates. Net loss/share was ($0.40) vs. ($0.41) and ($0.45) for Laidlaw and the Street. ALDX ended 4Q18 with cash of ~$94MM, enough to support its operations through 2020, in our opinion.

- **Reproxalap in AC Phase III study readout on-track in late 1Q19.** ALDX reiterated that the reproxalap in allergic conjunctivitis (AC) Phase III (ALLEVIATE) study readout is on-track in late 1Q19. ALDX will conduct a type C meeting with the FDA afterward before finalizing the 2nd Phase III study design, likely in 2H19. We expect no read-through (positive or negative) from the AC data to clinical study readouts of other indications, given the substantial differences in the nature of the disorders, the treatment design, and study endpoints.
- **Catalyst-rich period to come**. The ALLEVIATE study outcome is imminent in late 1Q19; reproxalap in NAU Phase III (SOLACE) study readout in 3Q19; and the first part of the topical reproxalap in SLS Phase III (RESET) study readout in mid- to late 2H19. Reproxalap in DED adaptive Phase III study should start in 1H19 with first part data readout in 1H20. ADX-2191 in proliferative vitreoretinopathy (PVR) adaptive Phase III study is to start in 2H19 with the first part data readout in 2020. ADX-1612 in post-transplant lymphoproliferative disorder Phase II trial could start in 2019; while ADX-629 in systemic autoimmune disease Phase I trial could begin in 2H19.
- **Reproxalap in DED Phase III study update.** Management indicated that the robust activities of 0.1% reproxalap treatment demonstrated by the prior Phase IIb trial is a clinical support for exploring a QID to BID tapper study. As such, ALDX believes the initial QID regimen might contribute to the early fast onset efficacy potentially as a loading dose. The subsequent lower dose could act as a maintenance regimen that would be effective while affording greater convenience to patient. For this study, the transition starts in week 4. We believe the potential 1H20 data readout, if robust, potentially would be one of more significant inflection points for ALDX shares. With substantially differentiated product attributes of reproxalap vs. other marketed DED therapies, we remain bullish on the commercial outlook despite the likely launch of Restasis generics, possibly in 2019.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses. We view the ALDX shares remain under-exposed and under-valued.

Trading Data:

Last Price (3/7/2019)	$7.64
52–Week High (9/26/2018)	$16.70
52–Week Low (7/30/2018)	$6.75
Market Cap. (MM)	$205.9
Shares Out. (MM)	21.686

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.42	-0.44	-0.45	-0.47	-1.78	N.A.
FY-18A	-0.43	-0.46	-0.52	-0.40	-1.79	N.A.
FY-17A	-0.37	-0.35	-0.32	-0.36	-1.40	N.A.
FY-16A	-0.51	-0.41	-0.38	-0.37	-1.65	N.A.

Source: Laidlaw & Company estimates

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Table 1: Estimated and reported 4Q18 results

4Q18 Estimates and Reported Results			
($,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$0.0**	**$0.0**	**$0.0**
Total op. profit (loss)	**($11,433)**	**($11,095)**	**($11,300)**
R&D	$8,275	$8,549	
SG&A	$3,158	$2,546	
EPS	**($0.41)**	**($0.40)**	**($0.45)**
Net income (loss)	($11,204)	($10,633)	($11,200)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Anticipated milestones in 2019 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Potentially interim Phase III (RESET) study results	**2H19**	****
		Potentially Phase III (RESET) study results	**2020**	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially report Phase III (SOLACE) study topline results	**3Q19**	****
	Allergic conjunctivitis	Potentially report Phase III (ALLEVIATE) trial outcome	**Late-1Q19**	****
		Potential Type C meeting with the FDA	**Mid-19**	***
		Potentially start 2nd Phase III trial	**2H19**	***
		Potential readouts of the second Phase III trial	**2020/2021**	***
	Dry eye syndrome	Potentially start Phase III trial	**1H19**	***
		Potentially start 2nd Phase III trial	**Late 2H19/2020**	***
ADX-103	Retina disease	Potentially start Phase I/IIa study	**2020**	***
ADX-2191	Proliferative vitreoretinopathy	Potentially start Phase III study	**2H19**	***
		Potential readout of first part of the Phase III study	**2020**	****
ADX-629		Potentially start safety Phase I study	**2H19**	***
	NASH	Potentially start Phase IIa study	**2H19**	***
	IBD	Potentially start Phase IIa study	**2H19/2020**	***
ADX-1612	Mesothelioma	Potentially start Phase II study	**2019**	***
	Lymphoproliferative immune disease	Start Phase II study	**2019**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

Yale Jen, Ph.D.
yjen@laidlawltd.com

Major Risks

Risks of clinical study failure could have a major impact on ALDX share value. Although promising aspects of the company's lead products, Reproxalap in the two indications under clinical trials; it remains too early to predict the safety and efficacy from the two ongoing and upcoming clinical studies. The clinical validation for these programs has not been established. The success of each study could illustrate Reproxalap treatment potential of separate disease areas. It is important that one or both studies demonstrate a positive outcome in order to increase the company's assets and shareholder value. Negative results of either of the clinical studies could impair shareholder value. Further, should these programs further advance into later clinical stage development, it remains too early to predict any potential success of such clinical trials. In SLS, it is possible that elevated fatty alcohol, instead of elevated aldehyde, affects the progression of the disease. If so, Reproxalap might not have the therapeutic effect on of elevated fatty alcohol levels. We view this to be a very modest risk, however.

Products may not be approved or reach anticipated sales. Aldeyra's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials. However, it remains too early to project whether any of these products will be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect ALDX shareholder value.

Limited product offering and further validation of technology represent limited diversification to investors. The major technology platform of ALDX is aldehyde trapping and the company currently has only one drug, Reproxalap, in two different delivery forms, in clinical studies. As such, ALDX has a very concentrated product offering portfolio and hence, exhibits limited diversification for investors. In addition, although aldehyde trapping is a novel and logical approach in drug development, it remains too early to gain greater buy-in within medical and investor communities since clinical validation remains very limited.

Additional financings could dilute shareholder value. Although the company had ~$94MM cash by end of 4Q18, ALDX could need more financial resources going forward if it wants to expand and further develop its pipeline. Should the product not receive FDA approval, or product revenue does not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Limited trading liquidity limits shareholder options. Given ALDX shares only entered the public market recently; daily trading volume and name recognition are relatively modest. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement

($'000)	2014	2015	2016	2017	1Q18	2Q18	3Q18	4Q18	2018	1Q19E	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E
Revenue																
Product revenue	0	0	0	0	-	-	-	-	0	-	-	-	-	0	0	2,944
Other revenue	0	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Total revenue	0	0	0	0	-	-	-	-	0	-	-	-	-	0	0	2,944
Costs of goods				0	-	-	-	0	0	0	-	-	-	0	0	265
Gross sales				0	-	-	-	0	0	0	-	-	-	0	0	2,679
Research and development	3,708	7,574	13,176	16,303	6,600	6,793	7,881	8,549	29,823	8,977	9,425	9,897	10,391	38,690	41,785	44,710
General and administrative	3,563	4,415	5,520	6,186	1,891	2,373	3,066	2,546	9,876	2,622	2,701	2,782	2,865	10,970	11,519	12,095
Marketing and sales															0	6,500
Total Operating Expenses	7,271	11,989	18,696	22,488	8,491	9,166	10,947	11,095	39,699	11,599	12,126	12,679	13,257	49,661	53,304	63,305
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(22,488)	(8,491)	(9,166)	(10,947)	(11,095)	(39,699)	(11,599)	(12,126)	(12,679)	(13,257)	(49,661)	(53,304)	(60,626)
Interest income	0	11	102	261	122	142	163	525	953	247	240	220	206	913	913	913
Other expenses		0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Interest expense	(244)	(113)	(106)	(113)	(28)	(26)	(29)	(64)	(147)	(26)	(26)	(26)	(26)	(104)	(104)	(104)
Total Other Income (Expense)	2,083	(102)	(3)	148	94	116	134	462	806	221	214	194	180	809	809	809
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(10,633)	(38,893)	(11,378)	(11,912)	(12,485)	(13,077)	(48,852)	(52,495)	(59,817)
Accretion of preferred stock	(333)	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Allocation of undistributed earnings to preferred s	0	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Deemed dividend	(4,054)	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Tax	0	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Net Income (Loss)	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(10,633)	(38,893)	(11,378)	(11,912)	(12,485)	(13,077)	(48,852)	(52,495)	(59,817)
Net Income (Loss) Applicable to Common Shareho	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(10,633)	(38,893)	(11,378)	(11,912)	(12,485)	(13,077)	(48,852)	(52,495)	(59,817)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.52)	($0.40)	($1.79)	($0.42)	($0.44)	($0.45)	($0.47)	($1.78)	($1.67)	($1.69)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.52)	($0.40)	($1.79)	($0.42)	($0.44)	($0.45)	($0.47)	($1.78)	($1.67)	($1.69)
Shares outstanding—basic	3,818	8,634	11,352	15,922	19,367	19,761	20,970	26,645	21,686	26,945	27,245	27,545	27,845	27,395	31,395	35,395
Shares outstanding—diluted	3,851	8,634	11,352	15,922	19,367	19,761	20,970	26,645	21,686	26,945	27,245	27,545	27,845	27,395	31,395	35,395
Margin Analysis (% of Sales/Revenue)																
Costs of goods														9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1519%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	411%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2059%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2032%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	24%	96%	76%	123%	54%	83%	36%	39%	26%	22%	30%	8%	7%
SG&A	67%	24%	25%	12%	10%	60%	108%	70%	60%	39%	14%	-9%	13%	11%	5%	5%
Marketing and sales																40%
Operating Income (Losses)	98%	65%	56%	20%	67%	72%	118%	57%	77%	37%	32%	16%	19%	25%	7%	14%
Pretax Income	-140%	133%	55%	19%	65%	70%	117%	53%	74%	35%	32%	15%	23%	26%	7%	14%
Net Income	-963%	26%	55%	19%	65%	70%	117%	53%	74%	35%	32%	15%	23%	26%	7%	14%
EPS	-172%	-44%	18%	-15%	18%	31%	61%	10%	28%	-3%	-5%	-12%	18%	-1%	-6%	1%

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Yale Jen, Ph.D.
yjen@laidlawltd.com

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RATINGS INFORMATION

3 Year Rating Change History

Date	Rating	Closing Price ($)

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)

Source: Laidlaw & Company Created by: Blue-Compass.net

Note stock rated Buy with $30 price target on 01/26/2015.

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	64.52%	25.81%	3.23%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.84%	1.61%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com