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EQUITY RESEARCH
Company Report

August 24, 2018

Aldeyra Therapeutics (ALDX - $8.65)

Healthcare/Biotechnology

Reproxalap in DED and AC Clinical Data Readouts Remain the Focus of Discussion on the Road

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

We recently hosted a handful of meetings with ALDX management and investors for a company update. Reproxalap ocular developments were the focus of most of the discussions. Highlights and key takeaways include:

- **Expectations of reproxalap in DED Phase IIb study readout.** Management reiterated that the topline result release is scheduled in late 3Q/early 4Q, roughly corresponding to late Sep. to early Oct. Identifying the signs and symptoms with positive trends by reproxalap therapy over the placebo-vehicle is the major objective of this study. Such outcome could facilitate the design of the next Phase III trials. Given the size of the Phase IIb study (100/arm vs. ~300/arm of the Xiidra pivotal study), achieving statistically significant outcomes of signs and symptoms are unexpected. Patients eligible for the study are of modest symptoms with disease history of 6 months or more and clinically would not response to vehicle treatment. The vehicle used is aqueous-based. Should positive trend of signs and symptoms be identified, ALDX could potentially start Phase III studies (need two) in 2019 after discussions with the FDA, and with possible completion (in 2020 or 2021). This time would coincide with the completion of the 2nd reproxalap in allergic conjunctivitis (AC) Phase III study. With a fast-acting attribute, reproxalap could potentially be differentiated from other DED treatments despite being launched after Restasis has already been genericized.
- **Reproxalap in AC Phase III study readout in late 4Q18/early 1Q19.** Supported by a robust Phase II study readout, we are bullish on the outcome of the Phase III study. Given the eyes are highly sensitive in DED patients, reproxalap treatment dose is lower, while higher doses of reproxalap are well tolerated in AC and NAU patients. The design of the 2nd AC Phase III study will employ an environmental setup for allergen delivery (the design of the 1st study uses challenge model).
- **ADX-1612 in malignant mesothelioma trial readout on 9/23-26.** Data will be presented at the International Association for the Study of Lung Cancer Conference. If positive, ALDX could start a pivotal clinical study later.
- **Clinical potential of RASP inhibitor gained greater buy-in.** With increasingly positive clinical data pouring in, more investors are starting to recognize the pathological consequence of active aldehyde in the inflammatory cascade and as such, the therapeutic value of removing them is better appreciated.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses.

Trading Data:

Last Price (8/23/2018)	$8.65
52–Week High (9/15/2017)	$11.90
52–Week Low (9/7/2017)	$4.00
Market Cap. (MM)	$160
Shares Out. (MM)	15.92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.43A	-0.46A	-0.50	-0.47	-1.86	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.
FY-15A	-0.32	-0.27	-0.35	-0.45	-1.40	N.A.

Source: Laidlaw & Company estimates

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Potentially interim Phase III study results	**1H19**	****
		Potentially Phase III study results	**2019/2020**	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially report Phase III study top-line results	**2019**	****
	Allergic conjunctivitis	Potentially report Phase III trial outcome	**4Q18/1Q19**	****
		Potential meeting with the FDA for second Phase III trial design and expectation	**2019**	***
		Potentially start 2nd Phase III trial	**2019**	***
		Potential NDA filing	**Late 2019/2020**	***
	Dry eye syndrome	Potentially report Phase IIb trial outcome	**Sep./Oct. 2018**	****
ADX-103	Retina disease	Potentially start Phase I/IIa study	**2019**	***
ADX-629		Potentially start safety Phase I study	**2019**	***
	NASH	Potentially start Phase IIa study	**2019**	***
	IBD	Potentially start Phase IIa study	**2019**	***
ADX-1612	Mesothelioma	Investigator sponsored trial data readout	**9/23-26, 2018**	***
	Ovarian cancer	Start investigator sponsored Phase II study	**2H18**	***
	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

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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 ~$42MM cash at the end of 2Q18, 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.

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Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement

($'000)	2014	2015	2016	2017	1Q18	2Q18	3Q18E	4Q18E	2018E	2019E	2020E
Revenue											
Product revenue	0	0	0	0	-	-	-	-	0	0	2,944
Other revenue	0	0	0	0	-	-	-	-	0	0	0
Total revenue	0	0	0	0	-	-	-	-	0	0	2,944
Costs of goods				0	-	0	0	-	0	0	265
Gross sales				0	-	0	0	-	0	0	2,679
Research and development	3,708	7,574	13,176	16,303	6,600	6,793	7,472	7,846	28,711	31,295	33,799
General and administrative	3,563	4,415	5,520	6,186	1,891	2,373	2,444	2,518	9,226	9,688	10,172
Marketing and sales											6,500
Total Operating Expenses	7,271	11,989	18,696	22,488	8,491	9,166	9,917	10,363	37,937	40,983	50,471
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(22,488)	(8,491)	(9,166)	(9,917)	(10,363)	(37,937)	(40,983)	(47,791)
Interest income	0	11	102	261	122	142	55	56	375	413	413
Other expenses		0	0	0	-	-	-	-	0	0	0
Interest expense	(244)	(113)	(106)	(113)	(28)	(26)	(27)	(27)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	148	94	116	28	29	267	304	304
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(9,889)	(10,334)	(37,670)	(40,678)	(47,487)
Accretion of preferred stock	(333)	0	0	0	-	-	-	-	0	0	0
Allocation of undistributed earnings to preferred s	0	0	0	0	-	-	-	-	0	0	0
Deemed dividend	(4,054)	0	0	0	-	-	-	-	0	0	0
Tax	0	0	0	0	-	-	-	-	0	0	0
Net Income (Loss)	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(9,889)	(10,334)	(37,670)	(40,678)	(47,487)
Net Income (Loss) Applicable to Common Shareho	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(9,889)	(10,334)	(37,670)	(40,678)	(47,487)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.50)	($0.47)	($1.86)	($1.61)	($1.81)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.50)	($0.47)	($1.86)	($1.61)	($1.81)
Shares outstanding—basic	3,818	8,634	11,352	15,922	19,367	19,761	19,961	21,961	20,263	25,263	26,263
Shares outstanding—diluted	3,851	8,634	11,352	15,922	19,367	19,761	19,961	21,961	20,263	25,263	26,263
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1148%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	345%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1623%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1613%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	24%	96%	76%	111%	41%	76%	9%	8%
SG&A	67%	24%	25%	12%	10%	60%	66%	68%	49%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	20%	67%	72%	98%	47%	69%	8%	17%
Pretax Income	-140%	133%	55%	19%	65%	70%	98%	49%	69%	8%	17%
Net Income	-963%	26%	55%	19%	65%	70%	98%	49%	69%	8%	17%
EPS	-172%	-44%	18%	-15%	18%	31%	55%	30%	32%	-13%	12%

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

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Additional information available upon request.

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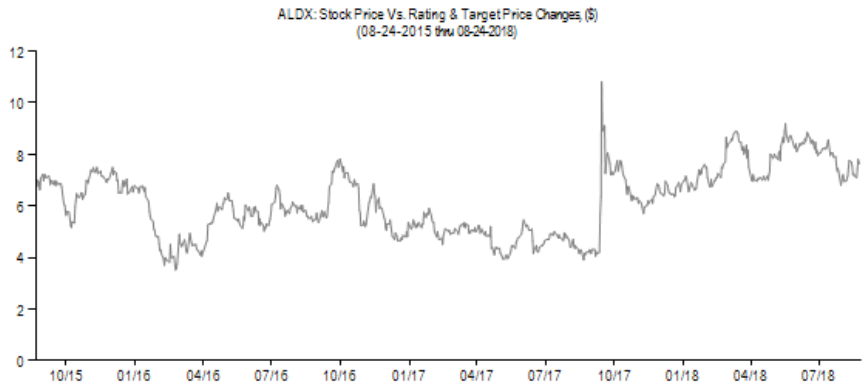
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)

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.	61.82%	21.82%	3.64%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.64%	1.82%	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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